IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Richmond Division

PHARMACEUTICAL COALITION FOR PATIENT ACCESS,

Plaintiff,

v.

UNITED STATES OF AMERICA

and

DEPARTMENT OF HEALTH AND HUMAN SERVICES, 200 Independence Ave., S.W., Washington D.C. 20201

and

OFFICE OF INSPECTOR GENERAL, 300 Independence Ave., S.W., Washington D.C. 20201

and

MICHAEL E. HOROWITZ, *In His Official Capacity as Inspector General of the United States Department of Health and Human Services*, 330 Independence Ave., S.W., Washington D.C. 20201

and

XAVIER BECERRA, *in His Official Capacity as United States Secretary of the Department of Health and Human Services*, 200 Independence Ave., S.W., Washington D.C. 20201

Defendants.

Civil Action No. 3:22cv714

Document Electronically Filed

COMPLAINT FOR DECLARATORY JUDGMENT AND INJUNCTIVE RELIEF

Plaintiff Pharmaceutical Coalition for Patient Access ("PCPA") brings this Complaint against the United States of America, the Department of Health and Human Services ("HHS"), the

Secretary of HHS ("Secretary"), the Office of the Inspector General ("OIG"), and the Inspector General (collectively, "Defendants") seeking a declaratory judgment and related injunctive relief.

INTRODUCTION AND SUMMARY

1. This case is about the urgent need of patients with cancer to secure access to Medicare[1] drugs and other health care services that could save their lives. Financially needy patients fighting cancer are often unable to secure access to critically important drugs and other health care services because they do not have the resources to pay the copayments, coinsurance, and deductibles that Medicare requires.[2] Research establishes (and the government itself agrees) that financially needy cancer and other patients fail to initiate life-saving therapies, or abandon them early, because they are obligated by the Medicare program to pay cost sharing amounts that are beyond their means. These access issues translate directly and alarmingly into patient mortality. There is a clear link between cost-sharing obligations and adverse health outcomes.

2. Plaintiff PCPA is a charitable organization led by an independent board of patient advocates and health care experts. PCPA has developed a program that would allow lower-income Medicare patients with cancer to secure access to Medicare Part D[3] covered drugs and other health care services they desperately need, using funding provided by drug manufacturers that have developed breakthrough and innovative drug therapies in the fight against cancer.

3. Pursuant to statute, 42 U.S.C. § 1320a-7d(b), PCPA filed requests for advisory opinions with Defendant OIG, that were based on regulatory guidance that OIG itself issued which

[1] The Medicare program is the federal health care insurance that provides health care coverage for the aged or various disabled persons. *See Biden* v. *Missouri*, 142 S. Ct. 647, 650 (2022) (per curiam).

[2] Copayments, coinsurance, and deductibles are referred to, collectively, as patient cost-sharing. 42 C.F.R. § 422.2 ("Cost-sharing includes deductibles, coinsurance, and copayments").

[3] Medicare Part D is a part of the Medicare program through which Medicare patients can obtain access for most drugs used on an outpatient basis. *See* Pub. L. No. 108-173, 117 Stat. 2066, tit. I (2003) (Part D). Medicare Part D was first implemented in 2006. 42 C.F.R. § 423.40(a)(4) (2005).

permits a coalition of manufacturers to provide assistance to Medicare Part D patients in financial need—exactly what PCPA stands ready to do.[4] PCPA originally hoped to launch the program before the Covid emergency was first declared in 2020, but OIG did not issue an opinion within the required 60-day period and patients with cancer were left without assistance as the Covid emergency worsened.[5]

4. Now, after three years, two requests, and multiple attempts to alter the PCPA proposal to address issues raised by OIG, OIG has (i) refused to issue a favorable opinion, (ii) declared that there was "no pathway" forward for PCPA (and the patients it seeks to assist), and (iii) concluded that PCPA's proposal constituted "prohibited remuneration" that "induces" the purchase of Medicare items and services under the Federal Anti-Kickback Statute ("the AKS"), which is a criminal law.

5. The AKS prohibits "illegal remunerations." 42 U.S.C. 1320a-7b(b). In a parallel fashion, it prohibits any person from (i) soliciting or receiving, or (ii) offering or paying, "any remuneration (including any kickback, bribe, or rebate)" that is (i) "in return for" or (ii) "to induce" a referral, purchase, lease, order or arrange for or recommend the purchase, lease or order of any "good, facility, service, or item" payable under a Federal health care program. *Id*.

6. Because the AKS is a felony criminal statute enforceable by a term of imprisonment of up to 10 years and a criminal fine up to $100,000, 42 U.S.C. 1320a-7b(b)(1), (2), PCPA and the individuals associated with it, as well as any prospective donors, cannot implement the program

[4] *See* HHS, OIG, Publication of OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623, 70627 (Nov. 22, 2005) ("2005 Guidance").

[5] *See* Office of Inspector General, Advisory Opinion No. 22-19 ("PCPA Advisory Opinion") (Sept. 30, 2022) (Ex. A).

that would assist patients with cancer in immediate and dire need because OIG has refused to issue a favorable advisory opinion.

7. Plaintiff brings this action under the Administrative Procedure Act ("APA") because OIG's conclusions in its Advisory Opinion dated September 30, 2022 are arbitrary and capricious, contrary to law, beyond statutory authority, and an abuse of discretion for multiple reasons. *See* 5 U.S.C. § 706; *Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 48 (1983); *ANR Storage Co. v. FERC*, 904 F.3d 1020, 1024 (D.C. Cir. 2018).

8. *First*, as a matter of law, the Advisory Opinion rejecting PCPA's program is contrary to law because PCPA's program does not violate the AKS. As OIG itself admits, the PCPA program is "agnostic" to the treatments selected independently by a patient's independent medical provider. *See* PCPA Advisory Opinion (Ex. A). Under PCPA's program, a needy patient with cancer may receive assistance for any one of a broad range of drug and non-drug cancer services after a course of treatment independently has been approved by the patient's medical doctor. *See* Pharmaceutical Coalition for Patient Access (PCPA) Advisory Opinion Request ("PCPA Second Request"), at 21 (Jan. 25, 2022) (Ex. B); PCPA Advisory Opinion at 4 (Ex. A). As such, the proposed program cannot, as a matter of law, satisfy the parallel "in return for" and "to induce" requirements of the AKS. Those key words are at the heart of defining a prohibited kickback under the AKS because they reflect an AKS requirement that any prohibited kickback involve a *quid pro quo* "in return for" or to "induce" the purchase of a specific item or service. *See Compensation*, Black's Law Dictionary (11th ed. 2019) (equating "compensation" with "remuneration"); *cf. BNSF Ry. v. Loos*, 139 S. Ct. 893, 905 (2019) (Gorsuch, J., dissenting) (citing Black's Law Dictionary for the proposition that "remuneration" means "*quid pro quo*," or "reward," or "recompense").

9. Indeed, where there are a wide range of options presented to a patient, as is the case here, OIG has itself conceded that the range of options would "sever any nexus" between the offered remuneration and a subsequent purchase under the AKS. *See* 2005 Guidance, 70 Fed. Reg. at 70627. In such circumstances, the remuneration is not "in return for" and does not "induce" a specific item or service.[6]

10. OIG's conclusion that "prohibited remuneration," PCPA Advisory Opinion at 12 (Ex. A), is present in the PCPA program also involves a separate misreading of the AKS statute. Contrary to the Advisory Opinion, the PCPA program does not result in prohibited remuneration because it does not involve any element of corruption, which is an element of an illegal kickback as reflected in the language, structure, and history of the AKS. The AKS limits the "illegal" and "prohibited remuneration" under the statute to "remuneration" defined by three corrupt examples, "kickbacks, bribes," and finally, "rebates." It is arbitrary and capricious to conclude that a charitable program offering a wide range of assistance to patients with documented financial need in an open and transparent fashion is corrupt, in any way.

11. *Second*, OIG's Advisory Opinion treats PCPA fundamentally differently than other similarly situated parties in an arbitrary and capricious manner. Under the APA, a federal agency is obligated to treat similar stakeholders in the same fashion. *E.g.*, *Burlington N. & Santa Fe Ry. v. Surface Transp. Bd.*, 403 F. 3d 771, 776 (D.C. Cir. 2005); *see also W. Deptford Energy, LLC v.*

[6] OIG's fundamentally incorrect reading of the AKS is only underscored by the fact that the PCPA Advisory Opinion is "internally inconsistent." *See ANR Storage*, 904 F.3d at 1024; *Banner Health v. Price*, 867 F.3d 1323, 1349 (D.C. Cir. 2017); *Dist. Hosp. Partners, LP v. Burwell*, 786 F.3d 46, 59 (D.C. Cir. 2015); *Air Transport Ass'n of Am. v. Dep't of Transp.*, 119 F.3d 38, 43 (D.C. Cir. 1997). As part of the same PCPA Advisory Opinion, OIG determined that the proposed program did not violate a civil statute that, in a substantial manner, overlaps the AKS prohibition. *See* PCPA Advisory Opinion at 21 (Ex. A). That statute, called the Beneficiary Inducement Statute ("the "BIS"), 42 U.S.C. 1320a-7a(a)(5), prohibits remuneration where the payment would "likely influence" a patient's choice of a provider, such as a pharmacy or hospital, for the provision of a Medicare or Medicaid item or service. OIG simultaneously (and inconsistently) found that a wide range of drug options would "influence" purchases under the AKS, but a wide range of provider options would not even "likely influence" a choice of provider.

FERC, 766 F.3d 10, 20 (D.C. 2014); *ANR Pipeline Co.* v. *FERC*, 71 F.3d 897, 901 (D.C. Cir. 1995). Here, OIG has permitted (1) other charities to secure funding from manufacturers to support patients using those manufacturers' products and (2) other providers to reduce or even completely waive copayments for their own patients. These stakeholders are protected by an Advisory Opinion, a regulatory safe harbor, or otherwise, but PCPA is denied any such necessary and critical protection.

12. *Third*, OIG's Advisory Opinion is arbitrary and capricious because it conflicts with OIG's own guidance. *E.g.*, *State Farm*, 463 U.S. at 42 (explaining that agency must provide "reasoned analysis" when "changing its course"); *Ramaprakash* v. *FAA*, 346 F.3d 1121, 1125 (D.C. Cir. 2003) ("An agency's failure to come to grips with conflicting precedent constitutes 'an inexcusable departure from the essential requirement of reasoned decision making.'") (quoting *Columbia Broad. Sys.* v. *FCC*, 454 F.2d 1018, 1027 (D.C. Cir. 1971)). OIG has specifically advised that, where certain safeguards are present in a "coalition" of manufacturers working together, such a coalition may provide financial assistance to patients without fear of AKS prosecution. *See* 2005 Guidance, 70 Fed. Reg. at 70627. That 2005 Guidance has not been rescinded or modified in any way by OIG. As discussed below, PCPA has, furthermore, complied in all material respects with that 2005 Guidance. Notwithstanding that, OIG has failed, in an arbitrary and capricious manner, to issue a favorable opinion to PCPA.

13. *Fourth*, in evaluating PCPA's proposal, OIG failed to consider the First Amendment rights of PCPA, as a charitable entity, in seeking to engage in protected solicitation of funds and in the protected speech it would make in securing funds and then dispensing assistance. *See Riley v. Nat'l Fed'n of the Blind*, 487 U.S. 781, 796 (1988); *Sec'y of State of Md.* v. *Joseph H. Munson Co.*, 467 U.S. 947, 967 & n.16 (1984); *Vill. of Schaumburg v. Citizens for a*

Better Env't, 444 U.S. 620, 632 (1980). OIG should have adopted a different view of the AKS to avoid violating PCPA's constitutional rights. *E.g.*, *Edward J. DeBartolo Corp. v. Fla. Gulf Coast Bldg. & Constr. Trades Council*, 485 U.S. 568, 575 (1988) ("[W]here an otherwise acceptable construction of a statute would raise serious constitutional problems, the Court will construe the statute to avoid such problems unless such construction is plainly contrary to the intent of Congress."); *accord Miller v. French*, 530 U.S. 327, 336 (2000); *Commc'ns Workers of Am. v. Beck*, 487 U.S. 735, 762 (1988); *NLRB v. Cath. Bishop of Chi.*, 440 U.S. 490, 499–501 (1979). Having failed to consider or adopt any "narrowly tailored" alternative to its sweeping Advisory Opinion conclusions, which flatly prevent PCPA from proceeding with its charitable mission, OIG has violated PCPA's constitutional rights.

14. OIG reads the AKS so broadly that it improperly criminalizes "innocuous, or even beneficial" conduct, 56 Fed. Reg. 35952, 35952 (July 29, 1991), that is itself protected by the First Amendment. The courts, including the Supreme Court, have not allowed the government to assert overly broad interpretations of criminal statutes. *E.g.*, *Skilling* v. *United States*, 561 U.S. 358, 410–11 (2010); *Liparota* v. *United States*, 471 U.S. 419, 427 (1985); *see also Yates v. United States*, 574 U.S. 528, 536 (2015) (plurality op.). This Court should take the same step here. For all of these reasons, this Court should declare that OIG's actions are arbitrary and capricious, without authority, an abuse of discretion, and in violation of the APA.

THE PARTIES

15. PCPA is a Virginia corporation organized under the laws of Virginia. The address for the registered office of the Corporation in the Commonwealth of Virginia, which serves as its principal place of business, is 4701 Cox Road, Suite 285, Glen Allen, Virginia 23060, Henrico County.

16. PCPA is organized and is operated exclusively for charitable, educational, and scientific purposes, within the meaning of Section 501(c)(3) of the Internal Revenue Code, and PCPA has filed with the U.S. Internal Revenue Service as a 501(c)(3) tax-exempt charitable organization.

17. As a non-profit charitable organization and advocacy group, PCPA seeks to provide financial assistance and public health information to a targeted group of medically indigent patients fighting cancer. PCPA seeks to respond to a recognized health care crisis, widely acknowledged by the federal government, researchers, providers, and patient advocates, in which patients with cancer are unable to afford medically necessary treatment for their disease.

18. PCPA has received its organizational funding and likely will receive a substantial portion or most of the costs of its assistance from pharmaceutical companies making and/or selling oncology drugs. PCPA is independent from its donors and prospective donors and is devoted to ensuring the highest standards of free choice in the selection of cancer treatments, as independently determined by the patient and the patient's treatment provider.

19. PCPA's Board of Directors has seven members. No donor or prospective donor to PCPA suggested or otherwise had any role in the identification, review, consideration, or selection of any board member. Board members are individuals with experience in appropriate patient advocacy organizations; were patients with cancer or their caregivers; or were individuals with clinical, public health or other relevant expertise, including relevant legal, not-for-profit, or financial experience. The Board of Directors were screened for conflicts of interest and are subject to on-going disclosure obligations to ensure that they are not subject to such conflicts of interest.

20. Defendant HHS is an executive department of the United States. HHS oversees the activities of the Office of Inspector General. HHS's headquarters are located in Washington, D.C. at 200 Independence Ave., S.W., Washington D.C. 20201.

21. OIG is a subdivision of HHS. Among other things, it is responsible for issuing advisory opinions analyzing the application of the AKS. Pursuant to the AKS, 42 U.S.C. § 1320a-7d(b) and 42 C.F.R. § 1008.1, *et seq*., OIG issues advisory opinions regarding a requesting party's existing or proposed business activities. OIG's headquarters are located in Washington, D.C. at 300 Independence Ave., S.W., Washington D.C. 20201.

22. Defendant Michael E. Horowitz is the Inspector General at HHS.[7] As Inspector General, Mr. Horowitz oversees the advisory opinions rendered by his office pursuant to the AKS. Defendant Horowitz maintains his office at 330 Independence Ave., S.W., Washington D.C. 20201. He is being sued in his official capacity only.

23. Defendant Xavier Becerra is the Secretary of HHS. The Secretary of HHS is the Inspector General's immediate superior and is ultimately responsible for the administration of the AKS. Defendant Becerra maintains his office at 200 Independence Ave., S.W., Washington D.C. 20201. He is being sued in his official capacity only.

JURISDICTION AND VENUE

24. PCPA brings this action pursuant to the Administrative Procedure Act, 5 U.S.C. §§ 701-706, the First Amendment to the United States Constitution, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

[7] Title 5, Section 702 of the United States Code provides that "[t]he United States may be named as a defendant in any such action, and a judgment or decree may be entered against the United States: *Provided*, That any mandatory or injunctive decree shall specify the Federal officer or officers (by name or by title), and their successors in office, personally responsible for compliance." 5 U.S.C. § 702.

25. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1361.

26. This Court has authority to grant the relief requested by PCPA pursuant to the Administrative Procedure Act, 5 U.S.C. §§ 701-706, the First Amendment, and the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

27. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(e) because Plaintiff PCPA resides in this judicial district.

STATUTORY AND REGULATORY BACKGROUND

28. This case arises as a consequence of the interaction of the AKS, an overlapping civil statute called the Beneficiary Inducement Statute ("BIS"), 42 U.S.C. 1320a-7(a)(5), and the provisions controlling the Medicare Part D program, originally enacted under the Medicare Prescription Drug, Improvement and Modernization Act of 2003 ("MMA"), Pub. L. No. 108-173, 117 Stat. 2066.

I. The Federal Anti-Kickback Statute ("AKS")

A. The Statutory Language

29. The AKS makes it a criminal offense to knowingly and willfully solicit or receive remuneration (including any kickback, bribe, or rebate) "**in return for** referring an individual to a person for the furnishing or arranging for the furnishing of any item or service" under a federally funded program, such as the Medicare program. 42 U.S.C. § 1320a-7b(b)(1)(A) (emphasis added). The statute also prohibits a solicitation or the receipt of remuneration "**in return for** purchasing, leasing, ordering, or arranging for or recommending" an item or service under a federally funded health care program. *Id.* § 1320a-7b(b)(1)(B) (emphasis added).

30. In addition, the AKS prohibits the knowing and willful offer or payment of "any remuneration (including any kickback, bribe, or rebate) . . . to any person **to induce** such person

. . . to refer an individual for the furnishing or arranging for the furnishing of any item or service" under a federally funded health care program. *Id.* § 1320a-7b(b)(2) (emphasis added). And the AKS also prohibits offers or payments "**to induce** a person . . . to purchase, lease, order, or arrange for or recommend" an item or service under a federally funded health care program. *Id.* (emphasis added).

31. The plain language of the AKS establishes a parallel set of prohibitions that are meant to address, in a parallel manner, both sides of a unlawful kickback. The statute addresses both "a person who solicits or receives" and "a person who offers and pays" a kickback. And the nexus or relationship between the "kickback" and a referral, purchase, order, or lease for a specific item or service requires that the kickback is "in return for" or "induce[s]" those actions. The presence of "remuneration" is not enough; that "remuneration" must be "in return for" or that "induce[s]" a specific item or service.

32. Accordingly, a number of courts have held that, in order for an AKS violation to occur, there must be a *quid pro quo* whereby the offer or payment of remuneration is provided for the explicit purpose of causing the specific purchase of an item or service.[8] This recognition of the proper scope of the statute springs from the plain language of the AKS itself.

33. In *United States v. Bruens* (D. Mass. May 2, 2007), for instance, the court described the applicable standard, with reference to the specific language used to define AKS' specific prohibitions:

> **To induce a purchase means** to offer or pay remuneration for the explicit purpose of causing a physician to purchase certain drugs **in return for** the payment of the remuneration. It is **not** a basis for conviction under the [AKS] that a person **merely hoped or expected or believed that purchases would ensue** from the

[8] *See* Jury Instructions, Trial Tr. at 53–54, *United States v. MacKenzie*, No. 01-CR-10350-DPW (D. Mass July 9, 2004); Jury Instructions, Trial Tr. at 72–73, *United States v. Bruens*, No. 05-CR-10102-JLT (D. Mass. May 2, 2007).

> payment of remuneration to a physician that was designed for other purposes. . . . A person does not violate the [AKS] by providing remuneration or other benefits solely as part of the routine cultivation of a business relationship, **rather than with the intent to induce specific purchases**.[9]

34. The court in *United States v. MacKenzie* (D. Mass. July 9, 2004) also made the point that a *quid pro quo* is required:

> It's not the purpose or within the scope of the [AKS] to prohibit transactions that reflect **the mere hope or expectation or belief** the that drug purchases might ultimately ensue from the business relationship . . . . Rather, the statutory requirement of improper inducement is satisfied only if remuneration . . . is offered or paid as a ***quid pro quo* for the specific purchase** of the drug.[10]

35. Similarly, in *United States v. Krikheli*, the government, in an AKS case, was "required to prove any payments . . . were made to induce referrals in a *quid pro quo* transaction."[11] The Second Circuit acknowledged that it is "accurate[]" to describe the law as obligating the government to "prove that the remuneration was offered or paid as a *quid pro quo* in return."[12]

36. The AKS does not prohibit all remuneration. The statute itself addresses "illegal remunerations" and "prohibited remuneration." *See* 42 U.S.C. § 1320a-7b(b)(1) (AKS); *id.* § 1320a-7d(b)(2) (advisory opinion statute). The "illegal" and "prohibited" remuneration targeted by the statute is then defined by the AKS by specifically referring to specific types of remuneration. *Id.* § 1320a-7b(b)(2) ("including any kickback, bribe, or rebate").

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[9] Jury Instructions, Trial Tr. at 72:15–73:4, *United States v. Bruens*, No. 05-CR-10102-JLT (D. Mass. May 2, 2007) (emphases added).

[10] Jury Instructions, Trial Tr. at 54:11–:22, *United States v. MacKenzie*, No. 01-CR-10350-DPW (D. Mass July 9, 2004).

[11] 461 F. App'x 7, 10-11 (2d Cir. 2012).

[12] *Id*. at 11. In a more recent case, *Pfizer v. HHS*, 42 F.4th 67 (2d Cir. 2022), the Second Circuit defined the term "inducement," but based on the facts of that case, which are dissimilar to those presented here, the court explicitly did not reach the question of whether the AKS requires a *quid pro quo*. *Id.* at 74 ("For the purposes of this appeal, we do not need to decide whether the AKS contains a quid pro quo element"). The *Pfizer* decision is discussed in greater detail below.

37. The first two of these defining examples, "kickback" and "bribe" are inherently corrupt in nature. The third term, "rebate," also includes an element of corruption when the term is read, as it must be, in its full and appropriate context.

38. The statutory history of the term "rebate" makes clear that Congress intended to address "rebates" that corrupt medical decision making. Thus, an earlier version of the statute prohibited "kickback[s]," "bribe[s]," and "rebate[s] of any fee or charge for referring any such individual" for services. Pub. L. No. 92-603, § 242(b), 86 Stat. 1329, 1419 (1972). In other words, the statute addresses rebates that divert federal funds from a provider to a third party, in exchange for a referral.

39. Congress later tightened the language to "kickback, bribe, or rebate," but the term "rebate" remained a shorthand for the same kind of conduct described in the earlier version. *See* H.R. Rep. No. 95-393, pt. 2, at 52–53 (1977) (discussing "kickbacks or bribes, **including rebates** or a portion of fees or charges for patient referrals") (emphasis added).

40. Moreover, the AKS includes exceptions that further define and limit the scope of the remuneration. *See* 42 U.S.C. § 1320a-7(b)(3). Immediately after the sections of the AKS that reference prohibited "rebates," the statute clarifies that not all such reductions in price are within the scope of the statute and its prohibition. Specifically, the very first statutory exception states that, despite the earlier reference to a "rebate," "a discount or other reduction in price" that is "properly" and "appropriately disclosed" is not "prohibited" or "illegal" remuneration under the statute. *Compare id.* § 1320a-7b(b)(1), *with id.* § 1320a-7b(b)(3)(a) ("[A] discount or other reduction in price obtained by a provider of services or other entity under [title XVIII or a State health care program] if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under [title XVIII or a State] health

care program."). Accordingly, only secret, corrupt rebates, in keeping with the criminal nature of the AKS and the references to both "kickbacks" and "bribes," are within the scope of the AKS. The statute requires both a *quid pro quo* and corrupt remuneration.

B. AKS Safe Harbors

41. Because Congress was concerned that OIG might criminalize beneficial conduct under the AKS, even with the statutory exceptions already in place, it also required OIG, by statute, to establish a process whereby the Agency would be required to issue regulatory safe harbors to protect beneficial conduct. *See* Pub. L. No. 100-93, § 14, 101 Stat. 680, 697; 42 U.S.C. § 1320a-7d(1). Defendant OIG itself acknowledged the concerns that gave rise to the safe harbor legislation in first exercising that authority in 1991. *See* HHS-OIG, Final Rule, 56 Fed. Reg. 35952, 35952 (July 29, 1991) ("[C]oncern has arisen among a number of health care providers that many relatively innocuous, or even beneficial, commercial arrangements are technically covered by the statute and are, therefore, subject to criminal prosecution").

42. Where a safe harbor applies, the conduct in question cannot be the basis of an AKS violation. 42 U.S.C. § 1320a-7d(1)(A) (explaining that safe harbor process designed to identify "payment practices that shall not be treated as a criminal offense under section 1320a-7b(b) of this title and shall not serve as the basis for an exclusion under section 1320a-7(b)(7)"). Accordingly, the availability of a regulatory safe harbor is a benefit to those provided such protection, and, under the APA, OIG is under an obligation, in conferring such benefits, not to treat similarly situated stakeholders in a dissimilar fashion.

43. As required by Congress, OIG has identified safe harbors under the AKS. Although asked a number of times by stakeholders to adopt a regulatory safe harbor to protect patient

assistance organizations and their donors when providing assistance to those in medical need with their co-payments obligations, OIG has failed to do so.

44. At the same time, OIG does permit "providers and suppliers"—meaning (i) pharmacies that dispense drugs, (ii) hospitals, (iii) ambulatory surgery centers, (iv) nursing homes, (v) clinics, and (vi) effectively every other entity involved in health care—to provide assistance to patients by waiving or reducing their copayment, co-insurance, or deductible obligations. 42 C.F.R. § 1001.952(k). OIG permits others to undertake such action, but not PCPA or its prospective drug manufacturer donors.

C. OIG's Advisory Opinion Process

45. Congress, in addition to requiring the issuance of safe harbors, has also required OIG, by statute, to establish a process whereby private parties can request an advisory opinion regarding the agency's enforcement policy, as applied to the requesting party's current activities or activities it proposes to undertake. 42 U.S.C. § 1320a-7d(b)(2); 42 C.F.R. § 1008.1.

46. The Secretary of HHS has issued regulations setting specific procedures for a requesting party's submission and the OIG's process and time table for rendering an advisory opinion. *See* 42 C.F.R. § 1008.1, *et seq*.

47. An advisory opinion, *inter alia*, addresses HHS' views of whether the proposed or actual conduct described in the submission constitutes "prohibited remuneration" under the AKS and if so, whether OIG nevertheless views such conduct as permissible. 42 U.S.C. § 1320a-7d(b)(2); *see also* 42 C.F.R. § 1008.1.

48. The OIG issues advisory opinions based on the facts that the requesting party presents as either its current practices or as a proposed course of conduct that it "in good faith specifically plans to undertake." 42 C.F.R. §§ 1008.1, 1008.11.

49. The Secretary is obligated to issue an advisory opinion regarding whether any activity or proposed activity constitutes "prohibited remuneration" or, regardless, will not constitute grounds for the imposition of sanctions under 42 U.S.C. §§ 1320a-7,[13] 1320a-7a, the BIS, or 1320a-7b, the AKS. *See id.* § 1320a-7d(b)(2); *see also* 42 C.F.R. § 1008.5.

50. Advisory opinions are binding on both the Secretary and on the party that requested the opinion. *See* 42 U.S.C. § 1320a-7d(b)(4). Where there is no applicable safe harbor, as is the case here, the party requesting an advisory opinion can operate safely without the risk of enforcement, only if the requestor acts consistent with a published OIG advisory opinion. *See* 42 C.F.R. § 1008.1.

51. Conduct that violates the restrictions described in an advisory opinion subjects a private party, whether an entity or the individuals associated with an entity, to the risk of criminal prosecution, administrative penalties, and other sanctions. *See id.* § 1008.18(c). AKS enforcement is aggressive generally and, in particular, with respect to organizations offering copayment assistance to patients in financial need and their manufacturer donors.

52. Once OIG renders an advisory opinion, the statute and regulations do not provide the requesting party with an administrative mechanism through which it can appeal OIG's advisory opinion. *See* 42 U.S.C. § 1320a-7d; 42 C.F.R. § 1008.45. The advisory opinion is final agency action. 42 C.F.R. § 1008.1 *et seq*.

53. OIG is required to answer a request for an advisory opinion in sixty (60) days. *See* 42 C.F.R. § 1008.43(c)(1)

[13] Section 1320a-7 excludes certain individuals from participating in any federal health care program. *Id.*

54. Where, as here, there is no applicable safe harbor, securing an OIG advisory opinion is essential to PCPA and other entities contemplating providing patient assistance to federally-funded healthcare program beneficiaries.

55. As a result, such entities have operated in reliance on advisory opinions (1) to convince donors that they may make donations without fear of criminal enforcement, and (2) to protect themselves and their own personnel in undertaking their charitable activities.

56. Prospective pharmaceutical manufacturer donors will not donate to PCPA or other charitable entities if those entities have not received a favorable advisory opinion from OIG, a fact that has been communicated repeatedly to Defendant OIG by PCPA and many others.

57. Operating a proposed patience assistance program without an advisory opinion is, therefore, functionally impossible because it would cut off PCPA and other charitable entities from necessary donor funding, thus preventing PCPA from engaging in the charitable activity and public health communications and assistance that are its First Amendment-protected mission.

58. The threat of administrative penalties or criminal sanctions for acting beyond the bounds of an OIG advisory opinion is clear. OIG's position is that it "believe[s] that Independent Charity PAPs raise serious risks of fraud, waste, and abuse if they are not sufficiently independent from donors." 79 Fed. Reg. 31120, 31123 (May 30, 2014) ("the 2014 Guidance").

D. OIG's Regulatory Guidance on Patient Assistance Programs

59. Defendant OIG has issued guidance that various requesters, including PCPA, have relied upon and from which OIG has taken its analysis under various advisory opinions.

60. Over the span of more than a decade, Defendant OIG has issued two advisory bulletins describing the only two pathways that OIG is willing to permit a charitable organization to receive funding from a pharmaceutical manufacturer to provide co-payment, co-insurance, or

deductible relief to financially needy patients. Those two pathways are referred to as the "Independent PAP Model" and the "Coalition Model." *See* 2005 Guidance, 70 Fed. Reg. at 70626.

1. The OIG's 2005 Guidance

61. OIG's 2005 Guidance was based on its acknowledgment that patient assistance programs involving industry "have long provided important safety net assistance to patients of limited means who do not have insurance coverage for drugs, typically serving patients with chronic illnesses and high drug costs." 70 Fed. Reg. at 70623–24. OIG further stated that it was "mindful of the importance of ensuring that financially needy beneficiaries who enroll in Part D receive medically necessary drugs."[14] Against this backdrop, OIG issued its guidance in light of "the importance of ensuring continued access to drugs for beneficiaries of limited means," both leading up to and following the implementation of the Medicare Part D benefit in 2006. *Id.* at 70624.

a. <u>The Independent PAP Model</u>

62. Under the Independent PAP Model, OIG stated in the 2005 Guidance that "cost-sharing subsidies provided by bona fide, independent charities unaffiliated with pharmaceutical manufacturers should not raise anti-kickback concerns, even if the charities receive manufacturer contributions." *Id.* OIG required Independent PAPs: (1) to be free from any manufacturer "influence or control," (2) to sever "any link" between the manufacturers funding and the beneficiary receiving assistance, (3) to provide assistance "without regard to the pharmaceutical manufacturer's interest and without regard to the beneficiary's choice of product, provider, practitioner, supplier, or Part D drug plan," (4) to use a "reasonable, verifiable, and uniform measure of financial need" in assessing patient need, and (5) to not provide to manufacturers data

[14] *Id*. at 70624.

that would allow them to "correlat[e] the amount or frequency" of their donations with subsidized prescriptions. *Id*. at 70626-27.

63. As part of its 2005 Guidance, OIG specifically addressed that Independent PAPs had developed funds from which financial assistance would be provided to patients with a particular disease where "only one pharmaceutical manufacturer (including its affiliates) . . . makes all of the Part D covered drugs for the disease." *Id.* at 70627 n.18. This "one to one" relationship between the fund's provision of financial assistance and disease treatment options, involving a single manufacturer, was not "determinative of an anti-kickback statute violation." *Id*. In such situations, the only specific, additional safeguard that OIG required for these funds was that "it would be important for the [single drug] PAP program to cover additional products or manufacturers as they become available." *Id.*

64. Such single drug situations are quite common. In accordance with this "single drug fund" guidance, OIG has issued advisory opinions to different charities permitting such funds, and multiple charities have, in fact, instituted such funds on the basis of the 2005 Guidance and those advisory opinions.

65. Unfortunately, as described below, the OIG's Independent PAP Model, including the single drug fund guidance, has proven inadequate to meet the needs of many patients. These funds typically provide assistance on a first come first served basis, and many run out of funding during the year. Some remained closed for years; some that reopen periodically do so for only a few days or even a few hours. In addition, despite the best efforts of the charities involved, most disease funds that have been opened under the Independent PAP Model have subsequently closed—providing no assistance to patients in need.

b. OIG's Coalition Model Guidance

66. Importantly, given the inability of the Independent PAP Model to meet the needs of many patients, the 2005 Guidance also provided an alternative pathway for patient assistance to be provided using pharmaceutical manufacturer funds under the Coalition Model. 70 Fed. Reg. at 70627. That guidance was a core, foundational element of the PCPA's advisory opinion requests.

67. In the Coalition Model Guidance, OIG describes a system in which manufacturers would, like in a single drug fund, "underwrite only the discounts on their own products." *Id.* The Coalition Model presented by OIG discusses "features that adequately safeguard against incentives . . . to favor one drug product (or any one supplier, provider, practitioner, or Part D plan)."[15] OIG explained that the program should include "a large number of manufacturers" that are "sufficient to sever any nexus between the subsidy and a beneficiary's choice of drug."[16] Each participating manufacturer was also to include all of its Part D products.[17] Finally, in encouraging "[o]ther safeguards," OIG suggested that Part D enrollees "pay a portion of their drug costs out-of-pocket,"[18] to continue to have an incentive to choose lower priced products, if available. This kind of "retained incentive" was not a required element of the Guidance, however.

68. In the 2005 Guidance, OIG acknowledged certain industry-led, multi-manufacturer programs had provided assistance to Part D enrollees consistent with the structure it laid out in the Guidance:

> [E]fforts by some in the industry to develop arrangements through which multiple pharmaceutical manufacturers would join together to offer financially needy Part D enrollees a card or similar vehicle that would entitle the enrollees to subsidies of their cost-sharing

[15] *Id.*

[16] *Id.*

[17] *Id.*

[18] *Id.*

> obligations for the manufacturers' products, typically in the form of discounts off the negotiated price otherwise available to the enrollee under his or her Part D plan.[19]

69. This was a reference to a coalition of manufacturers called TogetherRx. TogetherRx operated from June 2002 through December 2005 and was established by seven founding pharmaceutical manufacturer members: Abbott Laboratories, AstraZeneca, Aventis Pharmaceuticals, Bristol-Myers Squibb Company, GlaxoSmithKline, Johnson & Johnson, and Novartis Pharmaceuticals Corporation.[20] Not all of the major drug companies participated in TogetherRx.

70. TogetherRx was specifically recognized and favorably commented on by the Centers for Medicare and Medicaid Services ("CMS"), which is responsible for the Medicare Part D program, in a rulemaking that stated:

> Since January 2002, a number of manufacturers have announced discount programs designed to help low-income individuals access prescription drugs. . . . Seven manufacturers . . . have partnered together to form TogetherRx, which offers discounted prices to eligible persons. Individuals enrolling in these programs are able to purchase prescription drugs offered under the programs at discounted prices [at] retail pharmacies.[21]

71. Beyond acknowledging TogetherRx, CMS supported its effort by stating that the government "strongly supports providing assistance for low-income individuals regarding the purchase of prescription drugs."[22]

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[19] *Id.*

[20] *See New Pharmaceutical Alliance Offers Savings to Limited Income Seniors on More Than 150 Medicines through One Free Card*, TogetherRx Press Release (Apr. 10, 2002), https://web.archive.org/web/20040426170108/http://www.together-rx.com/newsroom/pr_041002.html.

[21] CMS, Medicare Program; Medicare-Endorsed Prescription Drug Card Assistance Initiative; Final Rule, 67 Fed. Reg. 56618, 56657 (Sept. 4, 2002) (emphasis added).

[22] *Id.*

72. OIG's 2005 Coalition Model Guidance acknowledged that the Coalition Model described there involved funding by manufacturers. Specifically, that Coalition Model Guidance stated that coalition model PAPs "operate so that the manufacturers effectively underwrite only the discounts on their own products."[23] The favorable commentary offered by both OIG and CMS on coalition models did not require a different funding mechanism.

73. As the Coalition Model Guidance itself states, it is the breadth of participation in a coalition that severs "any nexus" between the assistance offered and the products selected, not the funding source or mechanism. *Id.*

74. Accordingly, in such a model, there is no remuneration "in return for" or that "induces" purchase of a specific product, as required by the AKS, because patients are free to select from a broad range of options. As OIG has stated, where a coalition, regardless of its funding mechanism, includes "a large number of manufacturers," that is "sufficient to sever any nexus between the subsidy and a beneficiary's choice of drug."[24]

75. The Coalition Guidance as presented in the OIG 2005 Guidance remains in effect, never having been rescinded or modified by OIG.

2. The OIG's 2014 Guidance

76. In May 2014, OIG issued another Supplemental Special Advisory Bulletin. *See* 79 Fed. Reg. 31120. In this 2014 Guidance, OIG again acknowledged the importance of patient assistance programs: "PAPs have long provided important safety net assistance to such patients, many of whom have chronic illnesses and high drug costs." *Id.* at 31120.

[23] 2005 Guidance, 70 Fed. Reg. at 70627.

[24] *Id.*

77. Of the two pathways for copayment, coinsurance, and deductible assistance described in the 2005 Guidance, the 2014 Guidance only addressed the Independent PAP Model. In doing so, the OIG expressed certain concerns about the Independent PAP Model, but reiterated the 2005 Guidance in stating that creation of single drug funds was not "determinative" of an AKS violation. *Id*. at 31122.

78. Following the 2014 Guidance, OIG continued to permit single drug funds under advisory opinions.[25]

79. OIG did not rescind or modify the Coalition Model Guidance in the 2014 Guidance.

II. The Beneficiary Inducement Statute

80. The Beneficiary Inducement Statute ("BIS"), 42 U.S.C. § 1320a-7a, authorizes the imposition of civil monetary penalties against any person who gives remuneration to a person covered by Medicare or Medicaid, where that person "knows or should know" the remuneration is "likely to influence" the beneficiary's selection of "a particular provider, practitioner, or supplier." *Id*. § 1320-7a(a)(5).

81. The BIS overlaps with the AKS, but, in keeping with its imposition of purely civil penalties (rather than the criminal penalties under the AKS), the BIS's requirements are less rigorous than those of the AKS.

82. Where the AKS requires that a kickback under that statute be "in return for" or that "induce[s]" a specific item or service, the BIS merely requires that the payment be "likely to

[25] *See, e.g*., HHS, OIG, Notice of Modification of OIG Advisory Op. No. 11-05 (Dec. 29, 2015); HHS, OIG, Notice of Modification of OIG Advisory Op. No. 10-07, as modified (May 12, 2016) (stating the same); HHS, OIG, Modification of OIG Advisory Op. No. 07-18 (Nov. 2, 2015) (stating the same); HHS, OIG, Modification of OIG Advisory Op. No. 07-11 (modified Dec. 7, 2015) (stating the same); HHS, OIG, Modification of OIG Advisory Op. No. 07-06 (Dec. 29, 2015) (stating the same); HHS, OIG, Modification of OIG Advisory Op. No. 06-13 (Dec. 16, 2015) (stating the same); HHS, OIG, Notice of Modification of OIG Advisory Op. No. 06-10 (Nov. 2, 2015) (stating the same); and HHS, OIG, Notice of Modification of OIG Advisory Op. No. 04-15 (Jan. 6, 2016) (stating the same).

influence" the prohibited selection of a particular provider, practitioner, or supplier. *Id.* § 1320-7a(a)(5).

III. The Medicare Part D Program

83. The Medicare program for the elderly and certain disabled persons has four parts. Each part covers a different set of items or services or provides items or services in a different manner. Part D, the fourth part, provides coverage for a broad range of outpatient covered drugs, including many drugs that are essential in fighting cancer. The government supplies that coverage through private insurance companies under contract with CMS, and those companies are referred to as "Part D Plans."

84. Unfortunately, like the other Medicare "parts," the coverage provided under Part D for covered drugs is incomplete, with many beneficiaries expected to incur substantial costs to obtain the medications they need. The patchwork system of coverage and patient financial responsibility has changed over time, but the unfortunate reality remains that many patients are unable to afford access to medications. That is because these patients cannot afford the Part D copayment, deductible and other financial costs imposed on them by the program.

85. In 2022, for instance, a Medicare beneficiary was expected under Part D to pay, first, at the beginning of the year, a standard benefit deductible of $480.[26] In addition, for covered drug costs, a Medicare Part beneficiary is obligated under the standard benefit to pay 25% of covered drug costs until his or her total out-of-pocket costs reach $7,050. *Id*. At that point, however, the beneficiary's cost sharing does not end—the beneficiary may, in fact, be responsible for 5% of all additional co-insurance costs above that $7,050 out-of-pocket threshold. *Id*.

[26] State Health Ins. Assistance Program, *2022 Part D Standard Plan Cost-sharing*, La. Dep't of Ins., https://bit.ly/3NCgtbd (last visited Oct. 19, 2022).

86. An example will help to illustrate the point. One example involves a new, innovative oncology medicine that might cost $10,000 per month, and has a three-month course of therapy costing $30,000. A patient prescribed this product at the beginning of 2022 would have had to pay well in excess of $2,000 in deductibles and other costs, to use the product just for one month. Specifically, the patient would pay the $480 standard deductible, plus 25% of the remaining $10,000. Indeed, even after a patient reached the $7,050 out-of-pocket limit, the patient would continue to pay a monthly 5% co-insurance payment for each prescription. For other drugs, particularly ones with longer courses of therapy, the costs to the beneficiary would be multiples higher.

87. The recent passage of the Inflation Reduction Act ("IRA") promises some relief to Part D beneficiaries, but its assistance is implemented only on a delayed basis, and, even when fully implemented, the assistance that it provides will still leave many Part D beneficiaries unable to secure access to the cancer and other drugs they desperately need. *See* Pub. L. No. 117-169, 136 Stat. 1818. Bluntly stated, the IRA is not a complete solution to the crisis in access that needy patients with cancer face.

88. The IRA was passed by Congress on August 16, 2022, before OIG issued its negative advisory opinion to PCPA. *See id.* Under the IRA, Medicare Part D patients' out-of-pocket costs are capped at $3,250 in 2024, and $2,000 a year, beginning in 2025, but that amount is indexed and will increase in future years. Unfortunately, as discussed below, many cancer and other patients cannot afford out-of-pocket costs of $2,000 or even substantially less than $2,000 and will remain unable to obtain medically necessary medications, even after full implementation of the IRA. As explained below, coinsurance costs as low as $50 lead many patients not to initiate

treatment at all, to discontinue treatment early, or reduce dosing below their prescribed dosage.[27] A leading study of the impact of out-of-pocket obligations in Medicare Part D and other insurance programs on patients with cancer found that **41%** of all the tested patients with cancer abandoned their medication if their out-of-pocket costs were between just $500.01 and $2,000.[28]

89. Importantly, given the on-going risk to cancer and other Part D patients from the cost sharing obligations woven into the program, Medicare Part D specifically permits third parties to pay these very significant Part D costs on behalf of beneficiaries. The Part D statute and implementing guidance explicitly contemplate that Part D cost-sharing obligations may be paid on behalf of a Part D patient by another person or entity.[29]

90. As Defendant OIG itself has stated:

> [T]he Part D regulations make clear that beneficiaries may count toward their . . . assistance received from any source other than group health plans, other insurers and government funded health programs, and similar third party payment arrangements. The preamble to the Part D regulations explains that cost-sharing assistance furnished by a PAP, including a manufacturer PAP, will count toward a beneficiary's . . . expenditures.

2005 Guidance, 70 Fed. Reg. at 70625.

91. Although acknowledging that the Part D statute not only contemplates, but authorizes, that patient assistance from third parties, including manufacturers, can satisfy Medicare Part D cost sharing obligations, Defendant OIG nevertheless states that such payments by manufacturers, directly or through the interposition of wholly independent charities, can be a criminal violation of the AKS. *Id.*

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[27] Jalpa A. Doshi *et al*., *Association of Patient Out-of-Pocket Costs with Prescription Abandonment and Delay in Fills of Novel Oral Anticancer Agents*, 36 J. of Clinical Oncology 5 (Feb. 10, 2018), https://ascopubs.org/doi/pdf/10.1200/JCO.2017.74.5091?role=tab.

[28] *Id.*

[29] *See* 42 U.S.C. § 1395w-102(b)(4)(C)(ii); *see also* CMS, Medicare Prescription Drug Benefit, Final Rule, 70 Fed. Reg. 4194, 4239–40 (Jan. 28, 2005).

92. Part D beneficiaries are caught in the middle, unable to afford care and unable to secure patient assistance to meet the Part D-mandated cost sharing obligations.

PROCEDURAL BACKGROUND

93. As set forth in PCPA's submission to OIG, the PCPA program fills a pressing need by providing assistance to needy patients with cancer in a manner that complies fully with the AKS.

I. Despite the Dramatic Breakthroughs in Cancer Therapy, Patients with Limited Financial Resources Are Routinely Denied Access to Those Breakthroughs.

94. As discussed in PCPA's Advisory Opinion requests, pharmaceutical manufacturers are developing and have developed transformative therapies that are extending and saving patient lives by targeting deadly cancers. The American Cancer Society reports that, as a result of new treatments, the United States has witnessed a 27% decline in cancer death rates since such deaths peaked in the 1990s.[30]

95. If access is available to needy patients, progress is likely to continue. Cell and gene therapies, antibody-drug conjugates, immune checkpoint modulators, metabolic immunotherapies and vaccines all show tremendous promise.[31] In some cancer types, new therapies are leading to a "functional cure" (long-term remission) of the disease.[32] There were 1,300 cancer medicines and vaccines in development in 2020, before the impact of the pandemic.[33]

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[30] Stacy Simon, *Facts & Figures 2019: US Cancer Death Rate Has Dropped 27% in 25 Years*, Am. Cancer Soc'y (Jan. 8, 2019), www.cancer.org/latest-news/facts-and-figures-2019.html.

[31] Julian A. Marin-Acevedo *et al*., *Cancer Immunotherapy beyond Immune Checkpoint Inhibitors*, 11 J. of Hematology & Oncology 8 (Jan. 12, 2018), https://doi.org/10.1186/s13045-017-0552-6.

[32] Jorge Cortes *et al*., *Current Issues in Chronic Myeloid Leukemia: Monitoring, Resistance, and Functional Cure*, 10 J. of the Nat'l Comprehensive Cancer Network 3 (Oct. 2012), doi.org/10.6004/jnccn.2012.0184.

[33] *Medicines in Development for Cancer 2020 Report*, PhRMA Found. (Dec. 14, 2020), https://www.phrma.org/medicines-in-development/medicines-in-development-for-cancer-2020-report; *see also* Andrew Powaleny, *Report: More than 1,300 Medicines and Vaccines in Development to Help Fight Cancer*, PhRMA

96. Despite gains in groundbreaking therapies, patient access to treatment remains an insurmountable challenge in far too many cases due to prescription drug benefit designs, such as that of the Medicare Part D program, which can require patients to pay thousands of dollars. Many lower income patients simply cannot afford the out-of-pocket costs associated with these drug benefit designs. This is particularly true for Medicare patients with cancer, who are overwhelmingly retired with fixed incomes. Given their financial circumstances, many Medicare Part D patients simply cannot afford the copayments for innovative medicines.[34]

97. There cannot be any debate that cost sharing obligations create insurmountable barriers to access for many cancer and other patients. And, indeed, Defendants themselves concede this point. PCPA Advisory Opinion at 2 (Ex. A). As OIG acknowledges, "[m]any patients with cancer have significant financial burdens associated with their care." *Id*.

98. Defendant OIG's admission of the pressing need is merely a recognition of what numerous studies have found. Out-of-pocket costs under Medicare Part D and other insurance programs are associated with significantly higher rates of abandonment, reductions or delays in treatment initiation following a new diagnosis or disease progression, delays in refills, and earlier discontinuation.[35] These patterns occur in a number of areas, including various forms of cancers,

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Found. (Dec. 15, 2020), https://catalyst.phrma.org/report-more-than-1300-medicines-and-vaccines-in-development-to-help-fight-cancer.

[34] Liz Szabo, *As Drug Costs Soar, People Delay or Skip Cancer Treatments*, NPR (Mar. 15, 2017), www.npr.org/sections/health-shots/2017/03/15/520110742/as-drug-costs-soar-people-delay-or-skip-cancer-treatments.

[35] Jalpa A. Doshi *et al*., *Addressing Out-of-Pocket Specialty Drug Costs In Medicare Part D: The Good, The Bad, The Ugly, And The Ignored*, Health Affs. (July 25, 2018), www.healthaffairs.org/do/10.1377/hblog20180724.734269/full/; *see also* Stacie B. Dusetzina *et al*., *Cost Sharing and Adherence to Tyrosine Kinase Inhibitors for Patients with Chronic Myeloid Leukemia*, 32 J. of Clinical Oncology 4 (Feb. 1, 2014), https://ascopubs.org/doi/pdf/10.1200/JCO.2013.52.9123; Alfred I. Neugut *et al*., *Association Between Prescription Co-Payment Amount and Compliance with Adjuvant Hormonal Therapy in Women with Early-Stage Breast Cancer*, J Clin Oncol., 29(18) 2534–42 (June 20, 2011), https://pubmed.ncbi.nlm.nih.gov/21606426/.

such as chronic myeloid leukemia and metastatic renal cell carcinoma, and are exacerbated in the beginning of the calendar year when out-of-pocket costs are at their highest.[36]

99. Studies show the detrimental outcomes that result from non-adherence to prescribed oncology medicines, including increased hospitalizations and an overall increase in healthcare system expenditures.[37] Out-of-pocket costs are also associated with an increase in monthly mortality.[38]

100. In short, many patients with cancer, even though they are insured, are needlessly suffering and dying because they cannot afford to start and/or stay on the therapies prescribed by their health care providers due to out-of-pocket costs. A study of more than 38,000 Medicare Part D and other patients with cancer has found that almost half of all such patients abandon their medications when they are obligated to pay more than $2,000 out-of-pocket and that more than 40% abandon their medications if their out-of-pocket cost is between just $100.01 and $500.[39] Shockingly, 13% abandon their medication with costs as low as $50.01 to $100.[40]

101. Beyond that, the research establishes a clear relationship between out-of-pocket costs and mortality. For every 1% increase in a patient's co-insurance obligation, there is a 3%

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[36] Jalpa A. Doshi *et al*., *Addressing Out-of-Pocket Speciality Drug Costs*, *supra,* at n.35.

[37] Rachel Louise Cutler *et al*., *Economic Impact of Medication Non-Adherence by Disease Groups: A Systematic Review*, 8 BMJ Open 1 (2018), https://bmjopen.bmj.com/content/8/1/e016982; *see also* Dawn L. Hershman *et al*., *Early Discontinuation and Non-adherence to Adjuvant Hormonal Therapy are Associated with Increased Mortality in Women with Breast Cancer*, Breast Cancer Res Treat., 126(2) 529–37 (Apr. 2011), https://pubmed.ncbi.nlm.nih.gov/20803066/; Lucien Noens *et al*., *Prevalence, Determinants, and Outcomes of Nonadherence to Imatinib Therapy in Patients with Chronic Myeloid Leukemia: the ADAGIO Study*, Blood, 113(22) 5401–11 (May 28, 2009), https://pubmed.ncbi.nlm.nih.gov/19349618/; Amr R. Ibrahim *et al*., *Poor Adherence is the Main Reason for Loss of CCyR and Imatinib Failure for Chronic Myeloid Leukemia Patients on Long-Term Therapy*, Blood, 117(14) 3733–36 (Apr. 7, 2011), https://pubmed.ncbi.nlm.nih.gov/21346253/.

[38] Amitabh Chandra *et al*., *The Health Costs of Cost-Sharing*, Nat'l Bureau of Econ. Rsch. (Feb. 2021), https://www.nber.org/system/files/working_papers/w28439/w28439.pdf.

[39] Jalpa A. Doshi *et al*., *Association of Patient Out-of-Pocket Costs with Prescription Abandonment, supra,* at n.27.

[40] *Id*.

increase in mortality attributable to not initiating, limiting, or discontinuing drug therapy.[41] In other words, for every 1% increase in out-of-pocket costs, there is a threefold increase in mortality. That is both shocking and unacceptable.

102. The financial burdens associated with the cost of care are particularly significant for patients with cancer, many of whom also face a range of costs from health care facilities, physicians, additional providers, travel costs, and other drugs and medical devices. Moreover, many of those patients are frequently unable to maintain employment due to the progression of their disease or the demands of their treatments, which further underscores the need for financial assistance.

103. The resulting financial and other stresses, unsurprisingly, often impact a cancer patient's health outcomes. Mortality rates among patients with cancer who filed for bankruptcy are, on average, 79% higher than those of other patients. In sum, in many cases, patients are forced as a consequence of financial burdens to forgo treatment.[42]

104. These financial burdens and access needs, which were critical even before the pandemic, became only more so because of Covid. The Covid public health crisis had a devastating impact on patients with cancer, with a second crisis of undiagnosed cancers emerging in the pandemic's second year.[43] Preventive cancer screenings dropped between 86% to 94%

[41] Amitabh Chandra, *Health Consequences of Patient Cost-Sharing*, Law & Econ. Symp. (Apr. 28, 2021), https://laweconomicssymposium.com/wp-content/uploads/2021/05/les_webinar_health-consequences-of-patient-cost-sharing.pdf.

[42] Scott Ramsey *et al*., *Financial Insolvency as a Risk Factor for Early Mortality Among Patients With Cancer*, 34 J. of Clinical Oncology 9 (Mar. 20, 2016), https://ascopubs.org/doi/pdf/10.1200/JCO.2015.64.6620.

[43] Duaa Eldeib, *A Crisis of Undiagnosed Cancers is Emerging in the Pandemic's Second Year*, ProPublica (May 4, 2021), https://www.propublica.org/article/a-crisis-of-undiagnosed-cancers-is-emerging-in-the-pandemics-second-year.

during the early months of the pandemic,[44] and the National Cancer Institute has predicted nearly 10,000 excess deaths from breast and colorectal cancer in the next decade as a result of the pandemic.[45]

105. A recent American Cancer Society survey underscores the need for action. In a survey of 1,248 patients with cancer and survivors, conducted between October 22 and November 19, 2021, sixty-one percent of respondents reported that it was either very or somewhat difficult for them to afford their oncology care.[46] Unfortunately, results from a February 2020 survey reflected similar results, as well, even during a period before the pandemic took hold.[47]

106. Existing efforts to address access to Part D drugs for Medicare beneficiaries fighting cancer have proven fundamentally inadequate. OIG's guidance to date has been insufficient to address this clear, urgent, and longstanding need.

107. While organizations operating under the Independent PAP Model have been available for some Medicare patients suffering from particular forms of specified cancers, these resources have diminished substantially in recent years and, in many cases, are no longer available to the patients who need them.

108. A review of Independent PAP Model organizations performed in 2018 determined that 62% of the charitable disease funds listed on those organizations' websites were closed at that time. PCPA Second Request at 9 (Ex. B). When the study was repeated in 2021, an additional

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[44] *Delayed Cancer Screenings*, Epic Rsch. Network (May 4, 2020), https://ehrn.org/articles/delays-in-preventive-cancer-screenings-during-covid-19-pandemic.

[45] Norman Sharpless, *COVID-19 and Cancer*, 368 Science 6497 (June 19, 2020), https://science.sciencemag.org/content/368/6497/1290; *see also* Rachel Louise Cutler *et al*., *supra*, at n.37; Dawn L. Hershman *et al*., *supra*, at n.37; Lucien Noens *et al*., *supra*, at n.37; Amr R. Ibrahim *et al*., *supra*, at n.37.

[46] *Survivor Views: Affordability, Prescription Drugs, & Pain*, Am. Cancer Soc'y Cancer Action Network (Dec. 15, 2021), https://www.fightcancer.org/policy-resources/survivor-views-affordability-prescription-drugs-pain.

[47] *Id*.

fifteen of those funds had closed, bringing the total closures to almost 70%. *Id*. In other words, even if a fund had been created for a given disease,[48] only three in every ten funds assessed potentially offered support at the times that the studies were undertaken. *Id*. As a result, the access needs of low-income Medicare beneficiaries have become all the more acute.

109. The public websites of these organizations demonstrate that the problem continues unabated. One Independent PAP Model organization was selected at random. A recent review of its website showed that, for 71 listed disease funds, just 28% of all of those funds were currently "open." Funds for cancers listed as "closed" included basal cell carcinoma, bladder cancer, colorectal cancer, breast cancer, multiple myeloma, non-Hodgkins lymphoma, non-small cell lung cancer, ovarian cancer, prostate cancer, pancreatic cancer, renal cell carcinoma, and small cell lung cancer.

IV. PCPA Seeks to Help Financially Disadvantaged Patients Secure Meaningful Access to Cancer Therapy.

110. Over more than a three-year period, during which PCPA presented all of the evidence of the crisis in cancer care discussed above, PCPA has tried to work with OIG to find a solution to the crisis that patients with cancer face—all to no avail. Although PCPA has, for that entire period, had a workable Coalition Model solution developed and ready to implement, PCPA has been prevented from doing so because OIG is unwilling, under any circumstances, to proceed with a Coalition Model, despite having issued guidance recognizing that very model. PCPA cannot begin helping patients because the threat of criminal or administrative penalties prevents PCPA from even making solicitation communications to prospective manufacturer donors, which in any event, will not make any contributions in the absence of an OIG advisory opinion.

[48] There are many diseases, including many forms of cancer, for which there is no corresponding fund.

A. PCPA's First Request

111. On September 6, 2019, PCPA, then operating as a coalition of five pharmaceutical manufacturers (later more companies were added), requested an OIG advisory opinion for a Coalition Model patient assistance program. These manufacturers have developed many Medicare Part D covered drugs that benefit oncology patients in their fights against cancer.

112. PCPA underscored the critical and urgent need for such a program in its written request to OIG. The request compiled and summarized the extensive evidence demonstrating the extent and scope of the need and the mortality and adverse outcomes that patients with cancer experience where they are denied access to treatment because of cost-sharing obligations.

113. Citing OIG's 2005 Guidance on the Coalition Model, PCPA proposed a program that would cover a portion of the cost-sharing obligations of financially needy Part D patients for any Part D medication manufactured by any Coalition Model member, unless there was a generic alternative to an otherwise covered product. This ensured that any lower-cost alternatives with lower cost-sharing would not be disadvantaged by the assistance PCPA would offer. All cancer drug manufacturers, whether offering branded or generic drugs, would be invited to participate, and participating manufacturers would be required to provide support for all of their cancer medications. Ultimately, PCPA stated that it believed that the Coalition would include 90% or more or the Part D drugs used by patients with cancer. The Coalition would also permit any willing pharmacy to participate in the program, as long as it met basic requirements for network participation, such as accepting the card by which patient assistance would be made available.

114. Patients would only be considered for assistance after their prescriber had determined what medication, in his or her independent judgment, was the best option for the patient. To demonstrate financial need, patients would be required to meet certain reasonable,

uniform, and consistently applied criteria, including the patient's household income being less than 500% of the Federal Poverty Level,[49] a standard at or below the ones generally used by Independent PAP Model organizations already approved by OIG. Consistent with the Coalition Model Guidance, each manufacturer would be responsible for funding PCPA for the cost sharing amounts that it provided to needy Part D beneficiaries using that manufacturer's drugs.

115. The 2005 Coalition Model Guidance had explained that it would be beneficial, though not required, for a Coalition Model to require assisted patients to "pay a portion of their drug costs out-of-pocket" to "preserv[e] the beneficiary's incentive to locate and purchase equally effective, lower cost drugs."[50] Consistent with that portion of the 2005 Guidance, the PCPA proposal requires patients to remain responsible for $35 for each cancer drug prescription they receive.[51] Research establishes that Medicare Part D and other patients with cancer abandon their cancer medications 10% of the time with co-payment obligations as low as $10.[52]

116. The proposal also included multiple other safeguards over and above what was required by the 2005 Coalition Model Guidance. Those safeguards included: (1) the use of an independent administrator to run the program in accordance with the proposal, the 2005 Guidance, and any requirements contained in an OIG advisory opinion, (2) a prohibition on manufacturers

[49] The 2022 Federal Poverty Limit for a family of four is $27,750. The income limit for a family of four at 500% of the FPL is $138,750.

[50] 2005 Guidance, 70 Fed. Reg. at 70627.

[51] This figure was taken directly from the government's program permitting Medicare Part D patients to have all of the cost-sharing amounts for insulin, except $35 per prescription, paid by each participating Medicare insulin manufacturer. *See* CMS, *Part D Senior Savings Model* (Oct. 12, 2022), https://innovation.cms.gov/innovation-models/part-d-savings-model. There is no patient obligation in the government-sposored insulin program beyond the $35 payment per prescription. *Id.* By contrast, the PCPA program would require a patient with cancer to be responsible for a portion of the catasrophic level of coverage, *id*. at 15, 56 Fed. Reg 35, 952 (July 29, 1991), an obligation that, as emphasized by OIG, would provide an incentive for the patient to use the lowest-cost drug, such as a lower-priced generic drug, which would be available at a lower co-payment amount.

[52] Jalpa A. Doshi *et al*., *Association of Patient Out-of-Pocket Costs with Prescription Abandonment*, *supra*, at n.27.

marketing or advertising based on the program, (3) an affirmative obligation that participating manufacturers respect patient and prescriber decisions with regard to selection of therapies, (4) a requirement that, consistent with applicable privacy laws and regulations, the administrator of the program would identify beneficiaries participating in the program to Medicare, Medicaid, and the Part D Plans, so that they could use any and all utilization control mechanisms at their disposal to ensure only appropriate utilization was occurring and that the plan is not paying more than it believes appropriate for the drug therapy,[53] (5) a participating manufacturer must withdraw its branded product once a generic becomes available, (6) the development and implementation of a comprehensive compliance program, and (7) the retention of an auditor to perform compliance audits no less frequently than annually.

117. PCPA requested that OIG review its request so that it could launch the program in November 2019, which would have enabled it to make assistance available to patients beginning at the start of the 2020 calendar and Medicare Part D years. Defendant OIG was required, by its own regulation, to act within a 60-day period. If Defendant OIG had acted in that time and issued a favorable opinion, the assistance would have been available to patients when the Covid emergency was first being declared in January 2020.

118. Unfortunately, as the Covid emergency unfolded, the effect on cancer care was, predictably, devastating. As discussed above, *see* ¶ 104, Covid resulted in a crisis of undiagnosed

[53] In addition, drug manufacturers are under substantial constraint under the Part D program, as they are under private health care programs, to limit list prices and to offer substantial price concessions. Part D plans can and do fundamentally pressure oncology drug manufacturers by leveraging a host of tools that are readily at their disposal. Part D plans may continue to require that, before any drug is covered, (1) the patient must undergo specified diagnostic tests, (2) one or more other, lower cost drugs be tried and determined to have failed, (3) a biosimilar or generic product be used instead of a branded product, (4) a prior authorization be obtained to determine that the use of the drug is medically necessary or indicated, (5) the drug only be accessed through certain points of care, and (6) the patient's use of the drug is subject to additional treatment or monitoring requirements. Part D plans, CMS, and state Medicaid agencies will be informed by PCPA which patients are receiving support and for what products, so that they can employ any of these mechanisms or others at their disposal to restrict or condition coverage as they see fit.

and untreated cancers, as cancer screenings and other cancer care was unduly disrupted, threatening to result in nearly 10,000 excess cancer deaths associated with just two types of cancer.

119. OIG's actions substantially delayed a ruling on PCPA's request well beyond the 60-day deadline. The advisory opinion process unfolded extremely slowly, with OIG interposing questions to PCPA five different times, involving no less than 17 questions, many of which were duplicative of points already addressed in the request or in PCPA's earlier responses.

120. On October 7, 2020, more than a year after the request was submitted. and after several requests by PCPA for the review to be completed in light of the increasing adverse effect of the Covid emergency on cancer care, OIG and PCPA participated in a call. On that call, OIG indicated that its review had resulted in some concerns. Despite acknowledging the Coalition Guidance, OIG stated that it was reviewing the proposal with "fresh eyes" and had concluded that its review would be negative.

121. Although OIG stated that it saw no risk of overutilization in the proposal and that it did not see the proposal creating a risk or steering or anti-competitive impact, it stated that its concerns were (1) manufacturers might raise prices if all or substantially all products participated in the program, (2) PCPA's income eligibility threshold would result in too high a percentage of Part D beneficiaries participating in the PCPA program, (3) the Coalition would not be "independent" within the meaning of the separate Independent PAP Model Guidance, and (4) there would be a "1:1" relationship between a manufacturer's funding and the assistance to patients using that manufacturer's medications.

122. None of these stated objections was consistent with the Coalition Model Guidance, and many directly conflicted with that Guidance. Indeed, they were generally not even consistent with the requirements imposed under the Independent PAP Model for "single drug funds."

123. OIG stated that the proposal was not in complete compliance with that Guidance because manufacturers participating would include all their Part D cancer drugs, but not all their Part D drugs. After being asked if the inclusion of all Part D drugs in the proposal would alter the assessment, OIG stated that it saw no pathway forward for the proposal.

124. In subsequent communications, mindful of the crisis in cancer care access occurring as Covid raged, PCPA attempted to find modifications of the proposal that would satisfy OIG.

125. With those efforts proving fruitless, PCPA communicated to OIG on February 18, 2021 that, in response to OIG's reference to PCPA becoming "independent" of its potential manufacturer donors, PCPA would take that step. PCPA made that commitment even though "independence" was not a part of the Coalition Guidance. PCPA stated that it would take a number of months to reconstitute the organization, given the need to identify and recruit a new board of directors.

126. PCPA then made additional efforts to reach an agreement with OIG. PCPA presented a mechanism to address the stated "1:1" concern by expanding the scope of coverage to include assistance for additional non-Part D drug health care needs of patients with cancer, as single drug funds do under the Independent PAP Model. But OIG's view of the proposal remained unchanged.

127. After Defendant OIG stated it was prepared to move forward with a negative opinion unless PCPA decided to withdraw the request, PCPA decided the best course, at that time, to help patients with cancer was to withdraw the request, proceed with its reconstitution as an independent organization led by an independent board, and ask that board to consider mechanisms that could be incorporated into a new proposal that would further address OIG's stated concerns, even though none of the issues it had raised was part of the OIG's Coalition Model Guidance.

B. PCPA's Second Request

128. After months of work to identify, review for conflicts, and recruit a group of independent directors, a reconstituted PCPA began its review of the first request and set about the long task of reviewing the OIG's prior guidance to create a substantially revised proposal.

129. Led now exclusively by an independent board of directors, PCPA filed a second request on January 25, 2022. PCPA, in submitting the request, noted the urgent nature of the need, citing the growing risk to patients with cancer as Covid infections and related economic fallout worsened. *See* PCPA Second Request at 7 (Ex. B).

130. The Board also stressed its commitment to consider any concrete suggestions OIG might offer:

> At the outset of this Request, the Board of PCPA wishes to stress that it seeks a dialogue with OIG that addresses OIG's previously identified issues and results in providing patients with meaningful access to oncology therapies. We hope to engage with you to find a solution that OIG will approve, as there is no hope to address the public health crisis in cancer care without that approval.[54]

131. Given OIG's prior concern that setting the income eligibility standard for the PCPA program at 500% of the Federal Poverty Limit test would likely result in "too many" patients eligible for the program, the PCPA Board, despite its concerns about leaving needy patients without a means of assistance, reduced the eligibility to focus on those most in need. The revised eligibility standard was capped at 350% of the Federal Poverty Limit.[55] Accordingly, the Program, based on the revised eligibility standards, would apply to only approximately 31% of the Medicare Part D cancer population, or only approximately 11% of all new oncology cases. *See* PCPA

[54] PCPA Second Request at 2 (Ex. B).

[55] Where 500% of the FPL for a family of four in 2022 was $138,750, 350% of FPL was $97,125. The change from 500% FPL to 350% FPL results in a substantial reduction in the number of eligible patients (from 56% of Part D patients to just 31% of such patients).

Second Request at 11 (Ex. B). As PCPA noted, the actual percentage of patients participating would be lower than these numbers, as not all eligible patients would seek assistance. The Board's income eligibility threshold responded to OIG's earlier comments regarding its belief that the scope of patient assistance should be limited to create incentives for manufacturers to limit list price increases.[56]

132. Also in response to OIG's concerns, the Board increased the cost sharing obligations of patients receiving assistance under the program, requiring patients receiving assistance to pay in the catastrophic phase of Medicare Part D coverage. Depending on the particular patient's financial need, as reflected by his or her individual or family income, the patient was expected to pay 25% or 10% of the otherwise applicable catastrophic co-insurance obligation.[57]

133. PCPA also committed to addressing OIG's stated "1:1" concern[58] by following the OIG's directive for Independent PAP Model single drug funds and providing assistance to support programs designed to cover many non-Part D drug medical needs of patients with cancer. The coverage of these additional medical needs committed PCPA and participating manufacturers to supporting financially needy patients in the form of health insurance premium support offered to

[56] The Board noted that its eligibility standards were significantly narrower than those employed in CMS's insulin program (where manufacturers are currently permitted to provide copayment assistance and where there was no Federal Poverty Limit requirement) or under the Independent PAP Model (which typically uses a 500% of Federal Poverty Level or higher test). The Board also noted that in considering Part D legislation at that time, the Biden Administration had endorsed significant Part D cost limits, without a financial eligibility requirement. The IRA subsequently reduced Part D cost-sharing without any financial need test. Manufacturers fund those reductions in substantial measure based on a patient's use of each such manufacturer's products.

[57] No such catastrophic obligation is included in the CMS insulin program.

[58] In its Second Request, at 30, PCPA noted that the assertion that there was a "1:1" relationship between assistance provided to a patient and the payments made by a participating manufacturer was incorrect, as participating manufacturers would be responsible for the program's significant administrative costs.

oncology patients for Part B,[59] Part C,[60] or Part D premiums, as an individual may request. Accordingly, patients with cancer under this proposal could receive support even if they never used a participating manufacturer's Part D drugs or even if they treated their cancer through entirely non-drug therapies, such as surgery, radiation therapy, or any other non-drug service.

134. The annual commitment by PCPA and participating manufacturers to this additional funding of medical needs would be substantial: $15 million in the first year of operation and $20 million in the second year of operation, with the independent Board to determine the amounts to be set aside in subsequent years.

135. PCPA's Second Request also included all of the other safeguards associated with the First Request.

136. The Second Request also made a number of legal points. Specifically, PCPA highlighted that there was no *quid pro quo* within the meaning of the AKS created by the program, given the broad range of Part D drug options presented and the support for non-Part D medications or even non-drug items and services, with case citations. As a consequence, the request showed that there was no violation of the AKS present, regardless of whether the Second Request addressed OIG's policy concerns to its satisfaction.

137. The Second Request also presented the APA concern that OIG's analysis to date was contrary to law for multiple reasons, including that it was dissimilarly treating "single drug

[59] Medicare Part B provides coverage for physician and diagnostic services to diagnose and treat cancer and other diseases, including, for instance, the cost of a physician's professional service in excising cancer tumors or performing radiation therapy. Part B also covers the cost of non-Part D infused or injectable cancer drugs.

[60] Part C provides a managed care mechanism for Medicare patients to receive Part A and Part B coverage. Part A coverage provides items and services from institutional providers, such as hospitals. Part A would, among other things, provide patients with cancer with access to the technical and facility fee components of cancer surgery and radiation therapy.

funds" and PCPA, where single drug funds were permitted to address the "1:1" concern by funding other medical needs, but PCPA was not being permitted to do so.

138. The Second Request also discussed how OIG's analysis conflicted with other circumstances where the federal government permitted others to assist Medicare patients with cost-share obligations.

139. In addition, the Second Request stated that the OIG was obligated to issue a favorable opinion because of the request's compliance with the 2005 Guidance.

140. Finally, as PCPA was now a charitable organization, the Second Request underscored that OIG was obligated to consider its First Amendment rights and to ensure that its application of the AKS was narrowly tailored to address a compelling governmental interest. *See* PCPA Second Request at 34–35 (citing *Riley*, 487 U.S. at 796; *Schaumburg*, 444 U.S. at 632) (Ex. B).

141. Unfortunately, despite PCPA's repeated requests that OIG act in the 60 day time period required by regulation in light of the urgent need of patients with cancer, the process was again unnecessarily delayed. It ultimately took more than 8 months to complete, with three rounds of questions from OIG, including two rounds *after* OIG informed PCPA that it had no further questions about the PCPA program.

142. Following a conference call to discuss the status of the request, which occurred 5 months after the request was filed, PCPA wrote to OIG and summarized the call on July 8, 2022. Defendant OIG had communicated that it would issue a negative opinion unless the request was withdrawn, notwithstanding that OIG acknowledged that access to medicines is a problem and that PCPA's efforts, reflected in the Second Request, had, in fact, "lowered the risks" of the proposed program. Despite a discussion of OIG's views and PCPA's efforts to try to further address those

issues, OIG stated that it did not believe "there is any pathway to a favorable opinion." In particular, OIG emphasized its focus on the "1:1 issue," notwithstanding PCPA's inclusion of support for non-Part D drug cancer services and a willingness to potentially increase support for other medical needs. Taking OIG at its word that, no matter what modifications were made, OIG would not issue a favorable opinion on "any pathway," PCPA then reluctantly requested that OIG issue its written opinion.

143. OIG responded, stating that PCPA's email "restated some aspects" of the call, "but, of course it does not capture our discussion in its entirety. Due to this, it appears to misstate some of our discussion." Importantly, OIG did not identify any incorrect statement.

144. During the 8-month period the Second Request remained pending, legislation that was the precursor to the IRA was considered in Congress, and on August 16, 2022, the IRA was passed.

145. As the IRA neared enactment, OIG asked the following question about that legislation's possible impact on the PCPA proposal to which PCPA responded promptly:

> [OIG Question:] With the potential enactment of the Inflation Reduction Act, how, if at all, would the proposed program change?
>
> [PCPA Response:] No, the design would continue as set out in the request. The IRA would eliminate the need for patients to rely on some portions of the support offered by PCPA cutting down even further, and in a short period of time, on what was already a highly targeted program design focusing on patient need of the most acute nature. If there are modifications to PCPA's program design that OIG would find sufficient, in light of the IRA or otherwise, to permit a favorable advisory opinion, please specify.

146. OIG issued its negative opinion on September 30, 2022, 84 days after PCPA declined to withdraw its request, 8 months after that request was filed, and more than 3 years since the initial request.

V. OIG's Denial of the Advisory Opinion Request.

147. As indicated above, the Advisory Opinion does not dispute that (i) "[m]any patients with cancer have significant financial burdens associated with their care" or (ii) the evidence presented by PCPA that "prescription drugs are associated with higher rates of delaying treatment initiation following a new diagnosis or disease progression, delaying product refills, and earlier discontinuation of product use." PCPA Advisory Opinion at 2–3 (Ex. A). Further, OIG concluded that "[l]ike Requestor, OIG recognizes that some patients, including some Federal health care program beneficiaries, are unable or unwilling to access medically necessary oncology drugs due to the significant out-of-pocket costs incurred under the current Medicare Part D cost sharing structure." *Id*. at 10.

148. Notwithstanding all that, the OIG Advisory Opinion was negative.

149. At its core, the Advisory Opinion arrives at a negative outcome by coming to two essential conclusions: (1) the proposal supposedly violates the AKS, even though the proposal would not violate the BIS, and (2) OIG is not willing to permit the proposal to be implemented on the basis that it presents a "low risk" of fraud and abuse, even though it has permitted others to assist Medicare patients with their cost-sharing. *See id.*

150. With respect to its AKS analysis, none of its policy concerns about whether the proposal might affect drug pricing or affect some redesign of the Part D benefit, or any other consideration, is relevant. OIG's legal analysis on the question of whether or not the proposed model would violate the AKS is concise.

151. OIG asks simply whether the arrangement "involve[s] remuneration to an individual" and if that remuneration "induce[s] that individual to purchase, or arrange for the purchase" of an item or service. *Id*. at 13.

152. In concluding that the proposal violates the AKS, OIG purports to rely essentially on a single case, *Pfizer v. HHS*, 42 F.4th 67 (2d Cir. 2022) for the proposition that "'[t]he plain meaning of 'induce' is to 'entic[e] or persuad[e] another person to take a course of action'" PCPA Advisory Opinion at 13 n.31, 15 n.36 (Ex. A). It then argues that, because the proposal would "create an avenue" for manufacturers to indirectly "remove a financial barrier," the program "appears to be designed to induce the purchase of oncology drugs that are manufactured by a Funding Manufacturer." *Id*. at 14, 15.

153. In rendering its decision, OIG also concluded the AKS statute, citing the District Court opinion in *Pfizer*, does not require "a corrupt *quid pro quo* transaction." PCPA Advisory Opinion at 15 n.36 (citing *Pfizer Inc. v. HHS*, No. 1:20-cv-4920, 2021 WL 4523676 at *13 (S.D.N.Y. Sept. 30, 2021) (Ex. A).

154. Although OIG's legal analysis of the AKS was negative, the Advisory Opinion concedes that PCPA's program is "agnostic as to which Funding Manufacturer's Part D oncology drug a qualified enrollee would purchase." *Id*. at 15.[61]

155. Under its BIS analysis, Defendant OIG concludes that no BIS violation would occur under the proposal, notwithstanding that the BIS requires a less rigorous standard than the "in return for" and "to induce" requirements of the AKS. As OIG states, "Requestor certified that cost-sharing subsidies would be available without regard to a Part D enrollees' choice of provider, practitioner, Part D Plan, or supplier." *Id.* at 21. Given that the proposal "would work to ensure that a wide range of pharmacies would accept the subsidies," it is "[t]herefore" true, OIG concludes, that the remuneration offered by PCPA and by the manufacturers "would *not be likely*

[61] Indeed, because of the presence of support for additional medical needs, the proposed arrangement is, in fact, agnostic not just to what Part D drug may be purchased, but to whether the patient purchases any Part D product, a point made to OIG, which it also failed to address.

to influence a beneficiary to select a particular provider, practitioner, or supplier." *Id*. (emphasis added).

156. OIG also concludes that it will not use its enforcement discretion to permit PCPA to proceed, based on its policy concerns. OIG cited three primary reasons. First, OIG describes its own regulatory guidance on the Coalition Model by saying that it was "preliminary" and that it is now "informed by almost two decades of enforcement experience, various appraisals of the administration of the Medicare Part D program, and increasing drug prices." *Id.* at 16. OIG does not explain these points in any way or tie them to a need to introduce any new or different safeguard, not already a part of the Coalition Guidance. The Advisory Opinion nowhere states that the proposed arrangement does not comply with the Coalition Guidance.

157. With respect to the drug price question, OIG admits that "we cannot conclude that the cost-sharing structure proposed by Requestor would, in fact, result in increased drug prices and improperly increased costs to Federal health care programs." *Id*. at 19.[62]

158. The OIG also declines to provide a favorable advisory opinion based on the suggestion that the program would "effectively" permit PCPA and manufacturers to "redesign the current Part D . . . benefit." *Id*. at 17.[63]

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[62] The Advisory Opinion does not consider any of the pre-existing constraints manufacturers had under the pre-IRA law in attempting to raise prices, *see* PCPA Second Request at 26–27 (Ex. B). The Advisory Opinion also did not discuss the portion of the IRA, enacted before the Advisory Opinion was issued, that subjects manufacturers to a penalty if they attempt to raise prices above the rate of inflation on Medicare drugs, including Part D drugs. *See* Pub. L. No. 117-169 § 11102. It would be arbitrary and capricious for OIG not to consider the impact of existing law, and its disregard of existing law is "contrary to law" within the meaning of the Administrative Procedure Act. *E.g.*, 5 U.S.C. § 706; *State Farm*, 463 U.S. at 43.

[63] For the reasons set out, *supra*, at ¶¶ 89-91, that is incorrect. The Part D design specifically permits third parties, including any manufacturers, to address cost-sharing amounts. Independent PAP Model organizations, providers waiving co-payments, coinsurance, and deductibles, and advocacy groups covering the same items with provider funds are permitted to address cost sharing provided by OIG. In each case, those parties are paying amounts called for under Medicare benefit designs.

159. The Advisory Opinion does not address PCPA's First Amendment concerns or consider any, more narrowly-tailored alternative to its Advisory Opinion in light of PCPA's protected interests.

ANALYSIS

I. Defendant OIG's Advisory Opinion Is Unlawful Because It Is Contrary to the Plain Language of the AKS

160. The Administrative Procedure Act ("APA"), prohibits a federal agency from taking an action or denying a benefit on a basis that is arbitrary and capricious, contrary to law, or without authority. 5 U.S.C. § 706. Under the Advisory Opinion statute, Defendant OIG is specifically obligated to address proposed arrangements where the requestor seeks a determination that the arrangement does not "constitute[] prohibited remuneration" "within the meaning of [the AKS]." 42 U.S.C. § 1008.5. The Second Request explained why, based on the plain language of the AKS statute, PCPA's proposed arrangement does not result in "prohibited remuneration." Because the OIG's conclusion is contrary to the plain language of the statute, it should be set aside.

161. Defendant OIG's analysis of the proposed arrangement was defective and contrary to the plain language of the AKS for multiple reasons: (1) OIG failed to apply the AKS's "to induce" language and the *quid pro quo* requirement it creates; and (2) it did not require any element of corruption in defining what remuneration is prohibited by the AKS.

A. OIG Failed to Recognize that the AKS Requires a *Quid Pro Quo*.

162. An AKS violation must involve a *quid pro quo*. Because the PCPA proposal does not, it was arbitrary and capricious for OIG to conclude the proposal could violate the AKS.

163. As described above, Congress carefully structured the statute to create parallel prohibitions targeting a person who "solicits or receives" a kickback, 42 U.S.C. § 1320a-7b(b)(1), and a person who "offers or pays" a kickback, *id.* § 1320a-7b(b)(2). The presence of

"remuneration" is not enough, in either parallel case, for a violation to be present. In a parallel manner, the "remuneration" must be "in return for" or "to induce" the kickback-secured referral, purchase, lease, order or recommendation. *Id*. § 1320-7b(b)(1)-(2). Thus, the kickback must be "in return for" or "to induce" the specific sought after referral, purchase, or other act for a specific item or service.

164. A number of courts have recognized that the language and structure of the AKS thus create a *quid pro quo* requirement in which "remuneration" is solicited, offered, paid or received in exchange for a specific act.

165. "To induce a purchase means to offer or pay remuneration" for the purpose of "causing a physician [or other person] to purchase certain drugs in return for the payment of the remuneration."[64] Accordingly, "it is not a basis" for a violation of the AKS that a person "hoped or [even] expected," because of an offer of remuneration, "that purchases would ensue."[65] To constitute a violation of the AKS, the offer must be designed "to induce specific purchases." The AKS requires that remuneration be offered or paid "as a *quid pro quo*" for "the specific purchase of the drug" or other specific item or service.[66] In an AKS case, there must be proof that this requirement that an AKS violation induces a "*quid pro quo* in return" lies at the very core of the statute.[67]

[64] Jury Instructions, Trial Tr. at 72:15–72:18, *United States v. Bruens*, No. 05-CR-10102-JLT (D. Mass. May 2, 2007).

[65] *Id*. at 72:18–72:21.

[66] Jury Instructions, Trial Tr. at 54:21–:22, *United States v. MacKenzie*, No. 01-CR-10350-DPW (D. Mass July 9, 2004).

[67] *United States v. Kritheli*, 461 F. App'x 7, 10–11 (2d Cir. 2021).

166. Indeed, if such a requirement is not recognized, the "to induce" language specifically chosen by Congress becomes mere surplusage.[68]

167. The OIG, itself, has applied a *quid pro quo* analysis in assessing other advisory opinions under the AKS.[69]

168. The PCPA Program does not involve a *quid pro quo* and is not violative of the AKS. No "specific purchase" of any drug is made in exchange for the offer of assistance. Assistance will, as a threshold matter, only be offered to a patient only after the prescriber and patient have made a treatment decision and have selected a product.

169. Further, given that PCPA will cover a wide array of oncology drug options, without in any way preferring or recommending one agent over another, or indeed whether any drug is utilized, PCPA will be disinterested in what treatment an eligible patient's prescriber

[68] It is fundamental to statutory construction that all the words used by Congress should be given effect. *E.g.*, *TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001); *see also Duncan v. Walker*, 533 U. S. 167, 174 (2001); *United States v. Menasche*, 348 U.S. 528, 538–39 (1955) ("It is our duty 'to give effect, if possible, to every clause and word of a statute.'" (quoting *Montclair Twp. v. Ramsdell*, 107 U.S. 147, 152 (1883)). A reading of a statute that renders some statutory language a "mere surplusage" should, as a consequence, be rejected. *See TRW*, 534 U.S. at 31 ("We are 'reluctant to treat statutory terms as surplusage in any setting.'" (quoting *Duncan*, 533 U.S. at 174)). Defendant OIG's interpretation of "to induce" is so insubstantial that it is subsumed entirely into the "remuneration" prong of the AKS. OIG defines "remuneration" in the Advisory Opinion as "anything of value," PCPA Advisory Opinion at 13 n.30 (Ex. A), and it defines "to induce" as merely being capable of "enticing or persuading another person to take a course of action." *Id.* at 15 n.36. But if something has "value," it necessarily is always capable of "enticing or persuading." Under OIG's interpretation, there is, thus, no distinction between the "remuneration" and "to induce" requirements. The "induce[ment]" requirement collapses into the definition of "remuneration."

[69] *See Pfizer*, 42 F.4th at 74 ("HHS OIG expressly stated in the advisory opinion that the Direct Program would 'operate as *a quid pro quo*'"). OIG's erroneous conclusion that the PCPA proposal could violate the AKS is based almost entirely on its misplaced reliance of the Second Circuit's decision in *Pfizer*. OIG fails to appreciate the factually dissimilar nature of that case. The *Pfizer* case involved a situation where a manufacturer, without the involvement of an independent third party, offered assistance for one treatment option—and only one treatment option. *Id.* at 71. The program there was not "agnostic" to the choice of treatment selected. For this reason, the Second Circuit stated that, in that case, given those facts, "[w]e have no doubt" that a *quid pro quo* "exist[ed] here." *Id.* at 74. As a consequence, the court stated explicitly that, "[f]or purposes of this appeal, we do not need to decide whether the AKS contains a *quid pro quo* element." *Id.* Importantly, though, the Second Circuit stated that the term "induce" requires that it be directed to "a **certain** course of action." *Id.* at 75 (emphasis added). That, of course, is not the case in PCPA's proposed program. As the OIG has conceded, the program is "agnostic," PCPA Advisory Opinion at 15 n. 36 (Ex. A), as to the "course of action" a prescriber takes for his or her patient.

independently selects as the treatment option for that patient. There is no *quid pro quo* for any specific drug, or, indeed, for any particular item or service.

170. The Program is indifferent to the choice of therapies selected, whether covered by Parts A, B, C, or D of the Medicare program. Given the very broad-based nature of the support offered, regardless of what drug is chosen, or whether a drug is chosen at all, the Program is not designed to, and does not, in fact, "lead" or "move" a patient to select any "specific" option for treatment.[70]

171. Despite its negative conclusion in the Advisory Opinion, OIG's own prior analysis of a Coalition Model arrived at exactly the same conclusion. In a Coalition Model, generally, and particularly here, given the very broad-based nature of the offer of assistance proposed by PCPA, "any nexus" between the remuneration and the product selected is "severe[d]."[71] As OIG wrote there, "[a]lthough these programs would operate so that the manufacturers effectively underwrite only discounts on their own products," broad manufacturer participation is "sufficient to sever any nexus between the subsidy and the choice of drug."[72] This conclusion is even stronger here because of the substantial investment that will be made in supporting additional medical needs.

172. Because the AKS also requires that illegal "remunerations" or "prohibited remuneration" be corrupt in nature, it was also arbitrary and capricious for OIG to have concluded that the PCPA proposal could violate the statute in the absence of such corruption. The text, structure, and purpose of the statute clearly establishes this important limitation on the AKS.

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[70] Similarly, under the Program, participating manufacturers fund a mechanism which, at its core, does not tie the offer of assistance to the choice of a specific drug, but requires the manufacturer to support a program that supports patient and prescriber choice, regardless of the product selected.

[71] 70 Fed. Reg. at 702627.

[72] *Id*.

173. Although OIG contends that remuneration means "anything of value," the Advisory Opinion statute specifically refers to "prohibited remuneration,"[73] necessarily meaning that some remuneration is "prohibited" and some is not. Similarly, the heading that proceeds the prohibition language in the AKS itself refers to "illegal remunerations,"[74] again pointing to the necessary conclusion that some types of remuneration are within the scope of the statute, and some are not.

174. The statute itself then informs us about the types of remuneration that are included within its scope. Specifically, the word "remuneration," in the framing of the prohibition, references "any kickback, bribe, or rebate." The first two of these defining examples, "kickback" and "bribe," clearly are corrupt in nature, but so is the third, "rebate."

175. This is clear for two different reasons. First, statutory history for the AKS reveals the term "rebate" was used in a specific manner that inherently denoted a corrupt transaction. Specifically, in an earlier version of the AKS statute, the term "rebate" referred to a payment specifically to bribe a clinician into making a referral for a clinical service, where, of course, the physician should be acting in the best interest of the patient entrusted to him or her.[75]

176. Second, the scope of the word "rebate" can only be properly understood by reading that word in combination with the provision, integral to the AKS, that the prohibition language "shall not apply . . . to a discount or other reduction . . . if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made." 42 U.S.C. § 1320a-7b(b)(1)(A), (b)(3)(A). In other words, the language and structure of the AKS reflect that the term "rebate" means only a reduction in price that is not "properly" disclosed and "appropriately" reflected in

[73] 42 U.S.C. §1320a-7d(b).

[74] *Id.*

[75] *See* Pub. L. No. 92-603, § 242(b), 86 Stat. 1329, 1419 (1972).

"costs claimed or charges made." *Id*. § 1320-7b(b)(3)(A). Only corrupt, secret rebates are within the scope of the AKS, reinforcing that the "prohibited remuneration" referenced in the statute must be the kind of corrupt remuneration exemplified by "kickbacks, bribes, and [secret] rebates."

177. Thus, as discussed in *United States v. Zacher*, 586 F.2d 912, 916 (2d. Cir. 1978), the terms "kickback," "bribe," and "rebate," "each involves a corrupt payment . . . in violation of the duty imposed by Congress on providers to use federal funds only for intended purposes." *Id.*

178. The patient assistance that PCPA wishes to offer with the support of manufacturers does not involve corrupt remuneration. Most importantly, an independent physician must have already selected a product before any offer of assistance is made. Unlike in the case of "kickbacks" or "bribes," which at their core are designed to corrupt medical decision-making, subverting what should be a disinterested clinical decision into the corrupted product of the kickback or bribe, the PCPA program is specifically designed to create a neutral platform that does not interfere with physician decision-making, but merely enables access to a wide variety of product options once a treatment is selected by the medical provider.

179. And the PCPA program is the antithesis of a "rebate" that is not "properly" or "appropriately" disclosed. The PCPA program, fully disclosed in the advisory opinion request directly to OIG, requires transparency on an on-going basis. Consistent with applicable privacy laws, the patients receiving assistance will be disclosed to the Medicare and Medicaid programs and to the Medicare Part D plans, so the appropriateness of the medication or other health care serviced used can be fully monitored and controlled as the programs or plans deem fit.[76]

[76] The Second Circuit in *Pfizer*, 42 F.4th at 69, did not find that the AKS requires a corrupt transaction. Importantly, however, its decision, was based on its reading of the AKS language regarding "kickback, bribe, or rebate." The court interpreted that phrase based on a dictionary definition of "rebate" that the court found to be "neutral." *Id.* at 76. Based on this "neutral" definition, the court concluded that there was no corrupt element to the remuneration under the statute. But, in arriving at this conclusion, the Second Circuit failed to read the word "rebate" in context with the

180. The "to induce" language reinforces the need for an AKS violation to require a corrupt transaction. Although the Second Circuit applied another dictionary definition to conclude that "induce" has only the "neutral" meaning of "influence" or "entice," dictionary definitions of "induce" and "inducement" actually reveal two different meanings; one neutral, but another that requires corruption. For instance, *Oxford Learner's Dictionaries*, defines an "inducement" as "something that is given to someone to persuade them to do something," but then offers a separate definition that it is a "bribe."[77]

181. The context of the statute requires that the latter, not the former, use of "inducement" should apply here. The statute, after all, is an "anti-kickback" law that references "bribes" and undisclosed, secret "rebates." Even more fundamentally, the statute is a criminal prohibition, which subjects a person to a term of up to 10 years imprisonment. Only the definition that reflects an element of corruption is the one that properly reflects the text, structure, and purpose of the statute as a whole.

182. "Prohibited remuneration" under the statute must be understood as limited to corrupt exchanges, like a kickback, bribe, or secret rebate, and the PCPA's model is not corrupt. It is arbitrary and capricious for OIG to take the position that a charitable program, like PCPA's,

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provision that removes any "properly" and "appropriately" disclosed reduction in price from the ambit of statute. Read together, the only "rebates" included in the statute are those secret, corrupt rebates not "properly" and "appropriately" disclosed. The Second Circuit also argued that the key phase "includes" enlarged the examples of "kickback, bribery, or rebate" beyond those three examples. It, therefore, concluded that the single word "includes" excluded any corruption requirement. *Id*. The Second Circuit analysis, however, was logically flawed. It can be true that "includes" requires some transactions beyond the three specifically identified examples provided, but that does not undermine the point that the three examples define the type of remuneration that is "prohibited" and distinguish it from the "remuneration" that is not. For example, an undisclosed "discount" made at the time of purchase, is as corrupt as an undisclosed "rebate" made after the purchase. Such an undisclosed "discount" is included in the "prohibited remuneration," but its inclusion is still consistent with the corruption present in all of the defining examples. The Second Circuit based its conclusion that the use of the word "includes" necessarily meant "remuneration" could not be limited to corrupt remuneration, but that is a mistaken premise.

[77] *Inducement*, Oxford Learner's Dictionary, https://www.oxfordlearnersdictionaries.com/us/definition/american_english/inducement (last visited Nov. 7, 2022).

violates the AKS by providing assistance to patients with cancer with documented financial need in order to help them to secure medically necessary drugs and services, as independently determined by their physicians.

183. OIG's failure to recognize either a *quid pro quo* or a corruption element to the AKS creates an extraordinary risk of improper criminalization of innocent conduct. Indeed, the courts have repeatedly rejected overly broad interpretations of criminal statutes that threaten to result in overcriminalization.[78] In doing so, the courts have rejected government arguments that excessively broad interpretations of statutes should be permitted based on prosecutors' ability to exercise discretion in the cases they choose to bring. *Id.* OIG's misreading of the AKS presents a serious risk of improper criminalization of innocent conduct, leads to absurd results, and should not be permitted.

184. Under OIG's view of the statute, providing funds, from any source, to a patient of a federally funded health care program who uses those funds to secure any federally covered service, is the criminal act of offering or paying "remuneration" that has the capacity to "induce" a referral, purchase order, or other prohibited act. That cannot be what the AKS criminalizes, and this Court should not permit OIG to so distort the AKS. *See West Virginia v. EPA*, 142 S. Ct. 2587, 2607–08 (2022).[79]

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[78] *E.g.*, *Skilling*, 561 U.S. at 410–11; *Liparota*, 471 U.S. at 427; *see also Yates*, 574 U.S. at 536 (plurality op.).

[79] OIG's BIS analysis and conclusions are fundamentally inconsistent with its AKS analysis and conclusions, underscoring that OIG's interpretation of the AKS is deeply flawed. *See ANR Storage*, 904 F.3d at 1024; *Banner Health*, 867 F.3d at 1349; *Burwell*, 786 F.3d at 59; *Air Transp. Ass'n of Am.*, 119 F.3d at 43. Although there are some differences in the AKS and the BIS, these two statutes are overlapping in what they prohibit, and the differences in the two statutes, consistent with the purely civil nature of the BIS generally, make it easier to find a violation of the BIS, than it is to make out a violation of AKS. In the Advisory Opinion, OIG concluded that the Proposed Arrangement would "not be likely to influence" a beneficiary in his or her choice of a provider. PCPA Advisory Opinion at 21 (emphasis added) (Ex. A). Because, as the OIG put it, "any pharmacy willing" to participate could do so, the proposed program would not be even "likely" to "influence the selection of a provider." *Id.* But that conclusion necessarily applies under the AKS analysis. Any Part D cancer product can be a part of the program, and, in fact, the products and services supported are much broader than the Part D program, with additional medical assistance

II. Defendant OIG's Failure to Issue a Favorable Advisory Opinion Is Arbitrary and Capricious Because It Reflects Dissimilar Treatment of Similarly Situated Parties

185. The Administrative Procedure Act does not permit a federal agency to treat similar stakeholders in a dissimilar fashion.[80] Indeed, "Government is at its most arbitrary when it treats similarly situated people differently." *Etelson v. Off. of Pers. Mgmt.*, 684 F.2d 918, 926 (D.C. Cir. 1982). An agency may not treat "similarly situated parties differently" because doing so "is arbitrary and capricious" in violation of the APA. *E.g.*, *Bracco Diagnostics, Inc. v. Shalala*, 963 F. Supp. 20, 27–28 (D.D.C. 1997).

186. Defendant OIG has provided other stakeholders that are offering similar patient assistance as PCPA wishes to provide with protection from the risk of enforcement, including Independent PAP Model organizations, that have established single drug funds and providers that are permitted to reduce or waive copayments entirely. The unexplained and unjustified dissimilar treatment of PCPA by OIG is arbitrary and capricious and in violation of the APA.

A. Defendant OIG Dissimilarly Treats Independent PAP's Offering Single Drug Funds.

187. OIG has routinely allowed Independent PAP Model organizations to develop and implement single drug funds, where a single manufacturer can serve as the sole donor to that fund and to patients using that manufacturer's drug product. Many advisory opinions contain the following or substantially similar language:

> If the Charity establishes a fund for a disease for which FDA has approved only one drug or only the drugs made or marketed by one manufacturer or its affiliates, the Charity

providing support for non-Part D drugs and even for non-drug treatments. OIG's AKS and BIS analysis and conclusions are hopelessly conflicted.

[80] *See*, *e.g.*, *Indep. Petrol. Ass'n of Am. v. Babbit*, 92 F.3d 1248, 1258 (D.C. Cir. 1996).

> will provide support for the other medical needs of patients with the diseases.[81]

188. Such single drug funds are being operated currently, which PCPA supports. These funds operate right now with (1) broader Federal Poverty Limit eligibility than would be offered by PCPA, (2) less in the way of continuing, retained co-insurance obligations than the PCPA program would require, and (3) much narrower definitions of the relevant "disease" than PCPA's broad inclusion of all cancers.

189. These funds' inclusion of support for "other medical needs" does not distinguish these funds from PCPA, either, because under PCPA's Program, other medical needs will also be covered and in a very substantial fashion.

190. Independent PAP Model organizations are not required, as a condition of their approved advisory opinions, (i) to restrict manufacturer list prices (which they are powerless to do), (ii) to refrain from "altering" Medicare benefit designs (by providing financial assistance to patients that the statute expressly contemplates and encourages), or (iii) to take any other action that addresses any of OIG's stated concerns in PCPA's negative advisory opinion. *See* PCPA Advisory Opinion at 22 (Ex. A).

191. It is arbitrary and capricious for OIG to have provided advisory opinion protection to Independent PAP Model organizations using single drug funds, and to have denied that same benefit to PCPA.

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[81] *See, e.g.*, HHS, OIG, Notice of Modification of OIG Advisory Op. No. 11-05 (Dec. 29, 2015); HHS, OIG, Notice of Modification of OIG Advisory Op. No. 10-07, as modified (May 12, 2016) (stating the same); HHS, OIG, Modification of OIG Advisory Op. No. 07-18 (Nov. 2, 2015) (stating the same); HHS, OIG, Modification of OIG Advisory Op. No. 07-11 (modified Dec. 7, 2015) (stating the same); HHS, OIG, Modification of OIG Advisory Op. No. 07-06 (Dec. 29, 2015) (stating the same); HHS, OIG, Modification of OIG Advisory Op. No. 06-13 (Dec. 16, 2015) (stating the same); HHS, OIG, Notice of Modification of OIG Advisory Op. No. 06-10 (Nov. 2, 2015) (stating the same); and HHS, OIG, Notice of Modification of OIG Advisory Op. No. 04-15 (Jan. 6, 2016) (stating the same).

B. OIG Dissimilarly Treats Providers That Reduce or Entirely Waive Copayments.

192. As noted above, Defendant OIG provides safe harbor protection to providers, including Part D pharmacies, that reduce or even completely eliminate a patient's Part D copayments. 42 U.S.C. §1001.952(k).

193. Under this safe harbor protection, a provider can completely eliminate a copayment, whereas, under PCPA's program, a copayment is reduced, but beneficiaries would be required to retain a $35 copayment for each prescription and pay a portion of the catastrophic coverage, as well.

194. Pharmacies, including Part D pharmacies, may, under the safe harbor, reduce or entirely waive copayments, where no financial need has been demonstrated. *Id*. at (k)(3) (requiring only a "good faith" attempt to collect). By contrast, under PCPA's proposed program, any patient receiving assistance would have to demonstrate financial need.

195. Pharmacies, including Part D pharmacies, are not under the safe harbor required to restrict their list prices or take any other action responsive to the stated concerns in OIG's negative opinion issued to PCPA.

196. It is arbitrary and capricious for OIG to permit providers, including Part D pharmacies, to reduce or even completely waive Part D copayments, but not provide the same protection to PCPA.

III. The Failure to Issue a Favorable Opinion Was Arbitrary and Capricious Because PCPA's Proposal Complies with the 2005 Guidance.

197. Under the APA, an agency cannot depart from prior precedent without providing a justification for that departure. *E.g.*, *State Farm*, 463 U.S. at 42; *Ramaprakash*, 346 F.3d at 1125 ("An agency's failure to come to grips with conflicting precedent constitutes 'an inexcusable

departure from the essential requirement of reasoned decision making.'") (quoting *Columbia Broad. Sys.* v. *FCC*, 454 F.2d 1018, 1027 (D.C. Cir. 1971)). Under that legal standard, the PCPA Program should also have resulted in a favorable opinion because it complies with OIG's existing Coalition Model Guidance.

198. As discussed above, in its 2005 Guidance, OIG recognized "coalition model" PAPs. In its guidance, it described them as programs in which "multiple pharmaceutical manufacturers would join together to offer financially needy Part D enrollees . . . subsidies of their cost-sharing obligations" for the manufacturers' products. PCPA Advisory Opinion at 3 (Ex. A). The Part D Program's transition was accomplished, in part, with the assistance of TogetherRx, a coalition model program that formed the basis for the OIG's guidance. OIG acknowledged that these programs may operate such that the manufacturers underwrite only the discounts on their own products.[82]

199. *First*, the PCPA Program, as OIG's favorable BIS analysis confirms, quite clearly "contains features that adequately safeguard against incentives for card holders to favor one drug product (or any one supplier, provider, practitioner or Part D plan) over another."[83]

200. Specifically, because a patient must have a prescription for the underlying product or a need for other non-Part D drug or other non-drug services, such as a surgery or radiation therapy, before any assistance can be provided under the Program, a physician will have made an independent decision to treat the patient in the manner the physician deems most appropriate, before any assistance is offered. The PCPA program is, in the words of OIG, "agnostic" as to the choice of drug or other therapy, and the program will respect independent physician decisions with

[82] *See id.* This is not, however, the case for PCPA's Program, given the substantial commitment to Additional Medical Needs and the significant administrative costs involved in PCPA's program.

[83] 2005 Guidance, 70 Fed. Reg. at 70627.

respect to therapy selection at all times. PCPA and the Administrator will not advocate, recommend, or encourage between or among therapies.

201. Similarly, with respect to suppliers, providers, practitioners, or plans, the Program will be open to and welcome participation by all pharmacies, providers, practitioners, and plans. There will be no attempt to limit the involvement of any such entities or persons willing to accept the PCPA card. No favoritism or preference will be shown.

202. *Second*, the Program will include "a large number of manufacturers, including competing manufacturers," sufficient, in the words of OIG, to "sever any nexus between the subsidy and a beneficiary's choice of drug[s]."[84] Specifically, all identified pharmaceutical manufacturers with branded or generic oncology products will be invited to participate in PCPA[85] and at least ninety percent of existing Part D oncology utilization is expected to be available under the Program. Accordingly, PCPA's Program should include a minimum of fifty different, often competing drug products. *See* PCPA Advisory Opinion at 3–4 (Ex. A). In addition, an unlimited number of Medicare items and services, beyond Part D drugs, will be available for assistance through the Program's additional medical needs support.

203. *Third*, the Program would include all Part D covered FDA-approved oncology products of a participating manufacturer, branded and/or generic. Although the applicable OIG guidance on Coalition Model PAPs states that each manufacturer participating in a Coalition Model PAP should offer subsidies for all of its products covered by any Part D plan formulary and the proposed program focuses on cancer, PCPA offered to expand the program to require such

[84] *Id*.

[85] PCPA will also develop a process to assess periodically (but no less than once a year) overall manufacturer participation in the Program. In an effort to maximize manufacturer participation, PCPA will contact manufacturers of oncology products to offer them an opportunity to join and support the Program. These recruitment efforts will include manufacturers new to the oncology space and manufacturers of generic oncology products.

participation, but OIG stated that there was "no pathway to approval" of a favorable Advisory Opinion. An expansion of covered products to all Part D drugs was not material to OIG's analysis and was not the basis of its negative opinion.

204. In addition, although not a part of the three core safeguards identified in the Coalition Model Guidance, the Program will require patient cost-sharing as an additional program feature, with cardholders required to pay a portion of their copayment or coinsurance obligation. Finally, as indicated, *supra*, at ¶ 116, the PCPA proposal provides "additional safeguards," not required by the Coalition Model Guidance, but that are a positive factor under that Guidance.

205. Although OIG states in the PCPA Advisory Opinion that its 2005 Guidance was "preliminary" and that it has been informed by unspecified subsequent experience, OIG has never rescinded the Coalition Model Guidance or created any new, additional, or modified requirements. PCPA Advisory Opinion at 16 (Ex. A).[86] Given the opportunity to state any additional program components that would be sufficient to satisfy OIG in the three-year advisory opinion process with PCPA, OIG failed to identify any such new, additional, or modified requirement.

206. It is arbitrary and capricious for OIG not to provide a favorable advisory opinion under the Coalition Model Guidance.

[86] The entirety of OIG's analysis is as follows: "Our assessment of the coalition model presented in the Proposed Arrangement, unlike our preliminary commentary from 2005, is further informed by almost two decades of enforcement experience, various appraisals of the administration of the Medicare Part D program, and increasing drug prices." *Id.* OIG's unadorned reliance on the passage of time, references to unidentified "appraisals" of Medicare Part D, and boilerplate resort to the fact of increasing drug prices in no way justify departure from prior guidance designed to assist patients with cancer to receive life-saving treatments. *E.g.*, *State Farm*, 463 U.S. at 42 (agency must provide "reasoned analysis" when agency is "changing its course"); *Ramaprakash*, 346 F.3d at 1125 ("An agency's failure to come to grips with conflicting precedent constitutes 'an inexcusable departure from the essential requirement of reasoned decision making.'").

IV. Defendant's Failure To Issue A Favorable Advisory Opinion Violates PCPA's First Amendment Rights.

207. As PCPA explained to OIG, PCPA cannot solicit contributions from manufacturers to implement its Program in the absence of a favorable opinion from OIG. PCPA Second Request at 34 (Ex. B). Further, without those funds, PCPA cannot communicate with the public about the health care crisis in oncology access, the barriers to access created by Medicare, and how the Program is designed to address that crisis and those barriers, without regard to what drug or other therapy a patient and his or her caregiver may choose. *Id.* Manufacturers quite simply will not support the implementation of the PCPA Program unless OIG issues a favorable opinion.

208. "Charitable solicitations 'involve a variety of speech interests . . . that are within the protection of the First Amendment.'"[87] Truthful and non-misleading communications between a charity and its donors, including contribution solicitations, raise fundamental and long-recognized First Amendment issues.[88]

209. Simply put, the "[s]olicitation of charitable contributions is protected speech."[89] That is because "charitable appeals" for funding necessarily involve the "communication of information, the dissemination and propagation of views and ideas, and the advocacy of causes."[90] Indeed, "solicitation is characteristically intertwined with information and perhaps persuasive speech seeking support for particular causes or for particular views on economic, political, or social issues," such that "without solicitation the flow of such information and advocacy would likely cease." *Id.*

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[87] *Riley*, 487 U.S. at 788 (quoting *Schaumburg*, 444 U.S. at 632).

[88] *Schaumburg*, 444 U.S. at 632.

[89] *Riley*, 487 U.S. at 781.

[90] *Schaumburg*, 444 U.S. at 632.

210. Further, even when a charitable organization is not present, speech regarding prescription drug practices, medicine and public health issues warrant constitutional protection.[91] As the Supreme Court explained in *Sorrell*, the free flow of information "has great relevance in the fields of medicine and public health, **where information can save lives.**"[92]

211. Here, PCPA seeks to engage in free speech with the public on a host of oncology care related issues and how the Program can address those challenges. Topics of this speech and under the Program will include the critical issues of health disparity and health equity—the importance of which the Biden Administration itself has widely acknowledged. The chill imposed on PCPA, if it does not secure a favorable opinion, will prevent (1) PCPA from soliciting manufacturers to support implementation,[93] (2) the free flow of information with the public about the access crisis in oncology created by Medicare barriers to cancer care, and (3) PCPA's effort to address that critical public health crisis. This is, quite literally, "information [that] can save lives."[94]

212. These fundamental constitutional considerations underscore the arbitrary and capricious character of OIG's refusal to issue a favorable opinion here.

213. At the very least, given the serious First Amendment issues raised here, OIG was under an obligation to consider the First Amendment rights at issue and interpret the AKS in a manner that would avoid constitutional problems. Indeed, "where an otherwise acceptable construction of a statute would raise serious constitutional problems, the Court will construe the

[91] *Sorrell v. IMS Health, Inc.*, 564 U.S. 552, 566 (2011).

[92] *Id*. (emphasis added).

[93] Several manufacturers have supported the PCPA's Board's effort to develop and submit this advisory opinion request, but no manufacturer has expressed a willingness to financially support the implementation of the Program, unless a favorable advisory opinion is secured.

[94] *Sorrell*, 564 U.S. at 566.

statute to avoid such problems unless such construction is plainly contrary to the intent of Congress." *Edward J. DeBartolo Corp.*, 485 U.S. at 575; *accord Miller*, 530 U.S. at 336; *Beck*, 487 U.S. at 762; *Cath. Bishop of Chi.*, 440 U.S. at 499–501. Instead, OIG never considered PCPA's First Amendment rights or the First Amendment rights of potential donors, and never attempted to narrowly tailor its analysis or conclusions in light of those rights. *Compare* PCPA Second Request, at 34–35 (raising the First Amendment issues) (Ex. B); *with* PCPA Advisory Opinion (not mentioning the First Amendment) (Ex. A).

COUNT I

Defendants' Advisory Opinion Is Arbitrary and Capricious Because It Is Contrary to the Plain Language of the AKS.

214. The allegations in the paragraphs above are incorporated here by reference.

215. The Administrative Procedure Act allows a person suffering a wrong or adversely affected by an agency action to receive judicial review of the agency's action. 5 U.S.C. § 702. The reviewing court must set aside an agency's action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," and "contrary to constitutional right." *Id.* § 706(2)(A)-(B).

216. OIG's conclusion that the proposed program, as described in the Second Request, involves prohibited remuneration that induces a prohibited act within the meaning of the AKS is erroneous.

217. The proposed program, as described in the Second Request, cannot "induce" a prohibited act under the AKS because no *quid pro quo* involving a specific product occurs. There is no offer, solicitation, payment, or receipt of remuneration "in return for" or "to induce" a specific referral, purchase, order, or other act involving a specific product or service.

218. The proposed program provides a platform of products and services that offers a wide range of Part D and non-Part D drug and other medical service options. As such, it "severs" any link between a manufacturer donor and a patient receiving support, who is free, at all times, to select any treatment supported by the platform.

219. OIG erroneously relied on a factually dissimilar case that explicitly stated that it was not addressing the *quid pro quo* question in issuing its erroneous advisory opinion.

220. OIG's conclusion that the proposed program will "induce" a prohibited act is fundamentally in conflict with its conclusion, under the BIS, that the program is not even "likely to influence" a choice of provider.

221. OIG's misinterpretation of the AKS makes the "to induce" requirement for a violation "mere surplusage."

222. OIG's analysis and conclusions under the AKS are fundamentally inconsistent with its analysis and conclusions under the BIS, illustrating the arbitrary and capricious nature of OIG's analysis and conclusion.

223. OIG's misinterpretation of the AKS, a criminal provision of law, would criminalize wholly innocent conduct, including any effort by any charity to assist patients in federally funded health care programs, regardless of the source of donations.

224. As a consequence, OIG's misinterpretation of the statute infringes on PCPA's First Amendment rights and the First Amendment rights of potential donors.

225. OIG's erroneous conclusion that the proposed program involves prohibited remuneration under the AKS and its failure to issue a favorable advisory opinion are final agency action that results in harm to PCPA.

226. PCPA has exhausted all of its available remedies and/or pursuit of any further administrative remedies would be futile.

227. PCPA is entitled to challenge the OIG's misinterpretation of the AKS and failure to issue a favorable advisory opinion under 42 U.S.C. § 1320a-7d.

228. Defendants' erroneous conclusion that the proposed program could violate the AKS and its failure to issue a favorable advisory opinion is arbitrary and capricious, an abuse of discretion, and otherwise not in accordance with and in excess of Defendants' statutory jurisdiction, authority, and limitations.

229. PCPA has no adequate remedy at law.

230. PCPA is entitled to a declaratory judgment and injunctive relief confirming that the proposed program does not violate the AKS.

COUNT II

The Advisory Opinion Is Arbitrary and Capricious Because It Treats Similarly Situated Stakeholders Differently

231. The allegations in the paragraphs above are incorporated here by reference.

232. The Administrative Procedure Act allows a person suffering a wrong or adversely affected by an agency action to receive judicial review of the agency's action. 5 U.S.C. § 702. The reviewing court must set aside an agency's action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," and "contrary to constitutional right." *Id.* § 706(2)(A)-(B).

233. The APA requires a federal agency to treat similarly situated parties consistently. *E.g.*, *W. Deptford Energy, LLC,* 766 F.3d at 20; *ANR Pipeline Co.*, 71 F.3d at 901.

234. The OIG has determined that the AKS does not apply and has extended corresponding protection to Independent PAP Model organizations offering single drug funds, and providers that reduce or waive copayments under either advisory opinions or safe harbors.

235. PCPA is similarly situated to the entities that have received favorable opinions or other protection from OIG under the AKS.

236. Nevertheless, OIG has refused to provide a favorable advisory opinion to PCPA, leaving it at risk of criminal penalties under the AKS if it should move forward with its program.

237. PCPA's proposed program satisfies the conditions under which OIG has provided AKS protection to Independent PAP Model organizations offering single drug funds, and providers reducing or waiving copayments entirely, among others. PCPA's proposed program, in fact, often involves more limited assistance or additional requirements before assistance can be provided than the programs involving other stakeholders for which OIG has offered AKS protection.

238. PCPA has exhausted all of its available administrative remedies and/or pursuit of any further administrative remedies would be futile.

239. PCPA is entitled to challenge the OIG's failure to issue a favorable opinion under 42 U.S.C. § 1320a–7d.

240. Defendants' failure to issue a favorable opinion is arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with the law and in excess of Defendants' statutory jurisdiction, authority, and limitation.

241. PCPA has no adequate remedy at law.

242. PCPA is entitled to a declaratory judgment and injunctive relief confirming that PCPA is not subject to AKS enforcement if it acts in accordance with the proposed program.

COUNT III

Defendant OIG's Failure to Issue a Favorable Opinion to PCPA Is Arbitrary and Capricious Because OIG Failed to Follow Its Own Guidance

243. The allegations in the paragraphs above are incorporated here by reference.

244. The Administrative Procedure Act allows a person suffering a wrong or adversely affected by an agency action to receive judicial review of the agency's action. 5 U.S.C. § 702. The reviewing court must set aside an agency's action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," and "contrary to constitutional right." *Id.* § 706(2)(A)-(B).

245. As described above, OIG issued guidance in 2005 that permits Coalition Model programs to proceed without being subject to AKS enforcement so long as certain conditions are met.

246. OIG has not rescinded or modified its 2005 Coalition Guidance.

247. OIG may not depart from its prior guidance precedent without justifying that departure. Here, OIG offered no reasonable justification for departing from the 2005 Guidance and therefore OIG's refusal to issue a favorable advisory opinion in accordance with its own 2005 Guidance is arbitrary and capricious and contrary to law in violation of PCPA's rights. *E.g.*, *State Farm*, 463 U.S. at 42 (explaining that agency must provide "reasoned analysis" when agency is "changing its course"); *Ramaprakash*, 346 F.3d at 1125 ("An agency's failure to come to grips with conflicting precedent constitutes 'an inexcusable departure from the essential requirement of reasoned decision making.'") (quoting *Columbia Broad. Sys.* v. *FCC*, 454 F.2d 1018, 1027 (D.C. Cir. 1971)).

248. PCPA has exhausted all of its available administrative remedies and/or pursuit of any further administrative remedies would be futile.

249. PCPA is entitled to challenge the OIG's failure to issue a favorable opinion under 5 U.S.C. §§ 701-706 and 42 U.S.C. § 1320a–7d.

250. Defendants' failure to issue a favorable opinion is arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with the law and in excess of Defendants' statutory jurisdiction, authority, and limitation.

251. PCPA has no adequate remedy at law.

252. PCPA is entitled to a declaratory judgment and injunctive relief confirming that it may undertake the proposed program without being subject to AKS enforcement.

COUNT IV

Defendants' Failure To Issue A Favorable Advisory Opinion Violates PCPA's First Amendment Rights.

253. The allegations in the paragraphs above are incorporated here by reference.

254. The Administrative Procedure Act allows a person suffering a wrong or adversely affected by an agency action to receive judicial review of the agency's action. 5 U.S.C. § 702. The reviewing court must set aside an agency's action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," and "contrary to constitutional right." *Id.* § 706(2)(A)-(B).

255. The First Amendment provides that Congress shall make no law abridging the freedom of speech. U.S. Const. amend I. The First Amendment protects PCPA's lawful, truthful, and non-misleading communications with potential donors and the ability of charitable organizations to solicit contributions to support their charitable missions.

256. The First Amendment protects communications between a charity, the patients it has a mission to support, and its donors regarding public health and medical issues, such as the

barriers created by the Medicare Part D benefit design and the availability of patient assistance to address that flawed design.

257. This is "information that can save lives" and is entitled to a particularly high standard of protection, as a result.

258. In its negative Advisory Opinion, OIG failed to even consider PCPA's First Amendment rights and took no action to narrowly tailor the Advisory Opinion to address only a compelling governmental interest.

259. OIG's refusal to issue a favorable advisory opinion unlawfully infringes on PCPA's constitutional rights.

260. OIG's actions violate the Free Speech Clause of the First Amendment. Such restrictions were not narrowly tailored to serve a compelling interest.

261. The failure to issue a favorable opinion restricts PCPA's right to communicate with patients and prospective donors and is final agency action that results in current harm to PCPA.

262. PCPA has exhausted all of its available administrative remedies and/or pursuit of any further administrative remedies would be futile.

263. PCPA is entitled to challenge the OIG's failure to issue a favorable opinion under the First Amendment, 5 U.S.C. §§ 701-706 and 42 U.S.C. § 1320a–7d.

264. Defendants' failure to issue a favorable opinion, as it restricts constitutionally protected speech, is arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with the law and in excess of Defendants' statutory jurisdiction, authority, and limitation.

265. PCPA has no adequate remedy at law.

266. PCPA is entitled to a declaratory judgment and injunctive relief confirming that the negative advisory opinion is invalid as it infringes on PCPA's constitutional rights.

PRAYER FOR RELIEF

PCPA respectfully requests that this Court:

a. Enter a declaratory judgment that OIG's failure to issue a favorable Advisory Opinion as to the proposed arrangement is arbitrary and capricious and in violation of the Administrative Procedure Act, 5 U.S.C. §§ 701-706, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

b. Enter a declaratory judgment that the proposed arrangement, as set forth in PCPA's Second Request, is not subject to enforcement under and does not violate the Federal Anti-Kickback Statute. *See* 28 U.S.C. §§ 2201-2202, and 42 U.S.C. § 1320a-7b.

c. Enter a declaratory judgment that the proposed arrangement, as set forth in the Second Request, is entitled to a favorable advisory opinion with respect to enforcement under the Federal Anti-Kickback Statute. *See* 42 U.S.C. § 1320a-7b(b).

d. Enter a declaratory judgment that the negative advisory opinion is invalid as it violates the First Amendment rights of both PCPA and PCPA's prospective donors to engage in protected Free Speech.

Dated: November 9, 2022

Respectfully Submitted,

By: */s/ Robert D. Keeling*

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